QUALITY MANAGEMENT PLAN

for the

Maritime Environmental Resource Center

Version 1.0

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University of Maryland Center for Environmental Science
Chesapeake Biological Laboratory
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Solomons, MD 20688

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MARITIME ENVIRONMENTAL RESOURCE CENTER
Version 1.0

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1. INTRODUCTION

This document, the Quality Management Plan (QMP) for Maritime Environmental Resource Center (MERC), is the blueprint, of MERC's overall Quality Management System. The QMP describes MERC's quality system that will be employed in implementing MERC and provides its quality assurance (QA) policies and procedures; criteria for and areas of application; roles, responsibilities and authorities; and assessment and response. The guiding documents for the QMP are the American National Standards Institute (ANSI)/American Society for Quality Control (ASQC) E4-1994 *Quality Systems for Environmental Data and Technology Programs* and EPA QA/R-2, *March 2001, EPA Requirements for Quality Management Plans.*

1.1 Purpose

1.1.1 MERC Purpose

The purpose of MERC is to conduct independent, scientifically-sound, quality assured evaluations of ballast water treatment systems (BWTS) with regard to factors such as biological treatment performance, predictability/reliability, environmental acceptability, and safety. MERC testing protocols apply to the use land-based testing and are based on the International Maritime Organization (IMO) Guidelines for Approval of Ballast Water Management Systems (G8) and Procedure for Approval of Ballast Water Management Systems That Make Use of Active Substances (G9); and the ETV Generic Protocol for the Verification of Ballast Water Treatment Technologies (2010). Land-based testing, as defined by the IMO is a test of the BWTS carried out in a laboratory, equipment factory, or pilot plant including a moored test barge or test ship. Land-based BWTS verification testing is conducted in a manner to demonstrate consistent and predictable performance at full scale, simulating real world application and conditions. The objective is to provide information for stakeholders to make informed choices in selecting appropriate ballast water treatment technology for shipboard installations. Detailed information about MERC is presented at www.maritime-enviro.org.

1.1.2 Quality System Purpose

The purpose of the quality system described in this QMP is to establish policies, processes, and procedures that will ensure that the quality of data, products, and services provided by MERC meet or exceed meeting the data quality objectives (DQOs) established by the users of the data. It also ensures that all data collection and processing activities, performed by or under MERC's oversight, will result in the production of data that are both documented and of known quality, and can be used with a high degree of certainty by the intended user to support specific decisions or actions.

1.2 Scope

The scope of this QMP encompasses all activities that MERC and any test participants perform during the planning, testing, and reporting of MERC tests. The quality system defined in this QMP applies to personnel involved in, and activities conducted within, or for MERC. It contains the minimum requirements applicable to MERC activities. These include personnel qualifications and training, procurement of items and services, documents and records, computer hardware and software, planning, implementation of work processes, assessment and response, and quality improvement provisions.

1.3 Background

The primary focus of MERC is to evaluate the mechanical and biological efficacy, costs, and logistical aspects of ballast water treatment systems and to assess the economic impacts of ballast water regulations and management approaches. Invasions of coastal habitats by non-native aquatic species are increasingly common worldwide, are known to cause extensive ecological and economic damage, and have the potential to create human health concerns.

MERC has four main objectives:

- Provide technology developers/vendors with facilities and expertise for pilot-scale and shipboard evaluations of treatment systems;
- Provide regulatory agencies and classification societies with standardized, rigorous, and independent data on treatment system performance;
- Provide ship builders and shipping lines with information and decision tools to select the most appropriate ballast water treatment options; and
- Remove as much uncertainty as possible from emerging markets for treatment systems in order to accelerate the adoption of innovative technologies.

While the initial and primary focus of MERC is on ballast water treatment systems, the Center has the expertise, facilities, academic independence, and scientific integrity that will allow for testing and assessment of additional technologies and innovations related to Green Shipping, including hull fouling invasive species, port and vessel air emissions and alternative fuels, and gray and oily water treatments.

MERC conducts certification and R&D testing of ballast water treatment systems at three levels: lab bench proof-of-concept, land-based prototype, and shipboard validation/verification. Land-based testing is performed on the MERC Mobile Test Platform, which allows ballast water treatment systems to be evaluated in Baltimore MD (salinity 5 - 12 psu), Norfolk VA (salinity 18 - 25 psu) and/or Washington DC (Anacostia River, 0 psu) with one system installation. Mobile Test Platform specifications include:

Platform

- Length – 155’
- Width – 50’
- Draft – 3’ when tanks empty and 6’ when tanks full

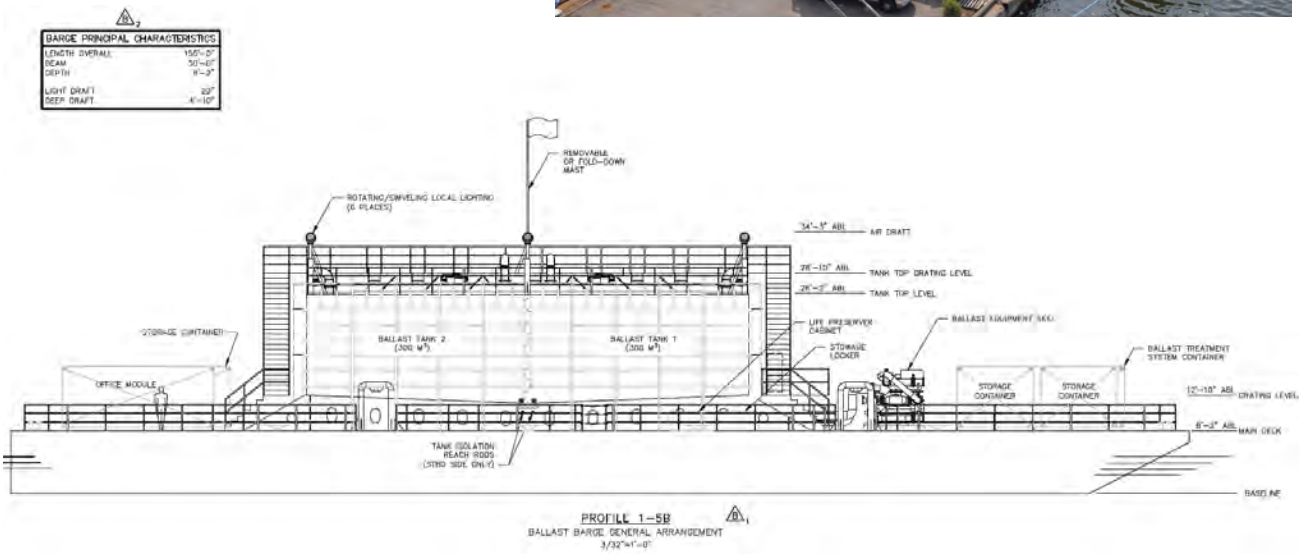
Facility

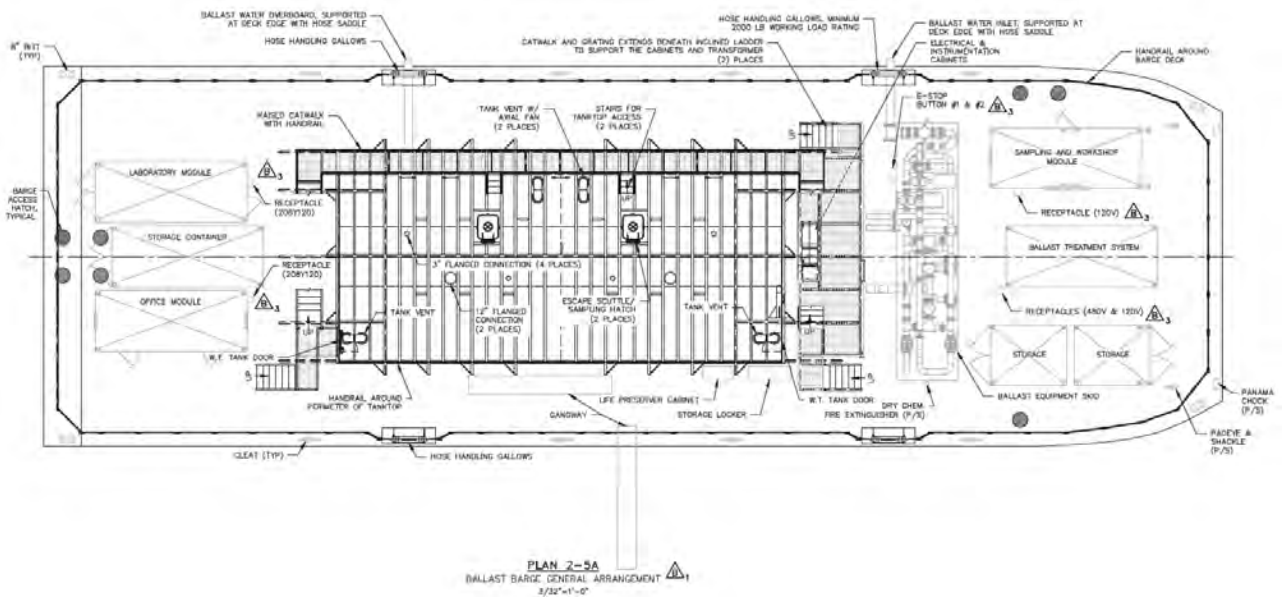
- Testing tanks – Two with capacity 310 m^3 each
- Pumps and piping – Two 60 hp centrifugal pumps with two eight-inch piping systems for versatility in moving ballast water and in tank filling and discharge
- Flow rates – Minimum of 100 m^3/hr and maximum of over 300 m^3/hr for each pump
- Flow pressure – up to 60 psi
- Municipal freshwater – up to 50 psi available for testing and cleaning
- Working space – onboard office, laboratory, sampling and storage containers
- Monitoring and controls – Integrated monitoring and control system for remote control of variable speed drives flow rates and pressure, plus data logging of valve positions, tank levels/volume, flow rate, pressure, sampling system operations, treatment system status, water quality parameters, etc.

Treatment System Requirements

- Treatments can be containerized (10’ or 20’) or as stand-alone units
- Ballast water connections – 8” intake and output
- Power provided for treatment systems: 100 Amps, 440 Vac, 60 Hertz, 3 phase; 50 Amps, 440 Vac, 60 Hertz, 3 phase; and 30 Amps, 120 Vac, 60 Hertz

Figure 2. MERC Mobile Test Platform.





2. MERC QUALITY SYSTEM MANAGEMENT AND ORGANIZATION

2.1. Quality Assurance Policy

It is MERC's policy to apply the highest level of QA to insure confidence that its services, products, and data meet or exceed meet the requirements of internal and external customers and that sufficient resources shall be available to develop and maintain the quality system. MERC will implement best practices in testing and assessment; ensure that organizations participating in testing have a quality system consistent with this QMP; ensure that testing is conducted according to the applicable Quality Assurance Project Plan (QAPP); and that test reports are supported by quality-assured data.

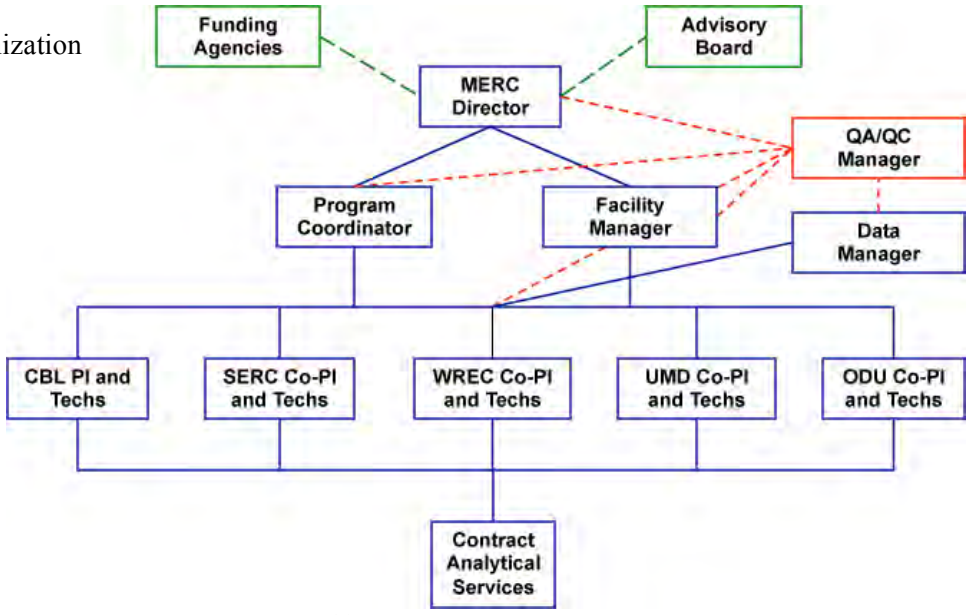
2.2. Allocation of Appropriate Resources to Support the Quality System

MERC supports implementation of this QA policy by supplying the resources, including staff, supplies, and support, needed to achieve the goals of each test of BWTS technology. MERC provides in-house and contracted expertise in quality assurance for all BWTS tests. Sufficient resources will be budgeted each fiscal year to ensure that both the Quality Assurance (QA) Manager and MERC staff are able to fulfill their responsibilities under this plan. The MERC Director and the QA Manager will work with MERC and MERC Partners' staffs to develop QAPPS to assure that the quality system is understood and implemented by all research and technical personnel working on the BWTS tests.

2.3. Organization and Quality System Roles, Responsibilities, and Authorities

MERC was created as a collaboration between the Maryland Port Administration (MPA) and the University of Maryland Center for Environmental Science's Chesapeake Biological Laboratory (CBL) and has received support from MPA, US Maritime Administration, National Oceanic and Atmospheric Administration, and American Bureau of Shipping. CBL is the lead institution and the MERC Director is a member of the CBL/UMCES faculty. Other MERC testing and research partners include the Smithsonian Environmental Research Center (SERC), University of Maryland College Park (UMD), University of Maryland Wye Research and Education Center (WREC) and Old Dominion University (ODU). The organization chart for MERC is provided in Figure 1.0 and shows key MERC staff and their reporting lines. Descriptions of key MERC staff are provided below. The names, mailing/email addresses, and phone/facsimile numbers of current staff are included in Appendix A. Executing an effective QA program demands the commitment of and attention of both management and staff.

Figure 2. MERC Organization



2.3.1. MERC Director and Principal Investigator

The MERC Director is responsible for meeting all technical, budget, and schedule goals for MERC. The MERC Director provides scientific leadership to MERC, including developing test designs, approving quality system documents and standard operating procedures (SOPs); and making all final decisions on MERC test facility engineering and operational modifications and upgrades. The MERC Director also has the authority to ensure that all applicable elements of the quality system as described in this QMP are understood and are implemented in MERC. The MERC Director serves as the primary point of contact for the MARAD Project Officer and the Maryland Port Authority.

2.3.2. MERC Co-Principal Investigator

Co-PIs from each partner institution are responsible for oversight of their technical staff assigned to MERC and the completion of specific tasks assigned to each institution, but is not typically involved in day-to-day testing activities. Co-PIs also provide peer-review and expert advice, guidance and insight on MERC programmatic and technical efforts.

2.3.3. MERC Program Coordinator

The Program Coordinator support the Director in planning and logistics of all MERC activities including the solicitation and review of applications for testing, scheduling and logistics of testing, and data compilation, analysis and reporting. The Program Coordinator also provides direct oversight of all testing staff during treatment system evaluations.

2.3.4. MERC Facility Manager

The Facility Manager supports the Director in planning and logistics of MERC testing and is responsible for the operations, maintenance and/or modification to the Mobile Test Platform. In consultation with the Director and Program Coordinator, the Facilities Manager is responsible for all final decisions made during testing and supports data compilation, analysis and reporting.

2.3.5. MERC Quality Assurance Manager

The MERC QA Manager reports directly to the MERC Director and functions with sufficient authority and technical resources to assure the independent implementation and oversight of the MERC quality system. The QA Manager is responsible for the preparation, approval and distribution of the QMP and QAPPs. The QA Manager also has the responsibility to ensure all applicable elements of the quality system as described in this QMP are understood and are implemented by MERC and MERC partner institutions. The QA Manager conducts and reports the results of assessments; and works with technical staff to address quality-related issues, identify corrective action, and quality system improvements.

2.3.6. MERC Data Manger

The Data Manager supports the Program Coordinator and Facilities Manager and is the person responsible for the compilation, review, management and storage of all data collected during MERC testing.

2.3.7. MERC Advisory Board

The Advisory Board consisting of individuals who represent a cross-section of diverse constituents and stakeholders, provides insight and recommendations on various MERC activities, and serves as peer-reviewers of MERC applications and reports, on an as needed basis.

2.3.8. Vendors

The responsibilities of vendors who choose to participate in testing may include any of the following. In addition, these test-specific responsibilities will be defined in the QAPP:

- review and provide comments on the draft Test Plans;
- approve the final Test Plan prior to test initiation;
- provide technology(ies) for evaluation during the test;
- provide all equipment/supplies/reagents/consumables needed to operate their technology(ies) for the duration of the test;
- provide representative(s) to operate their technologies during testing and/or provide written instructions and training for routine operation of technologies by MERC staff.
- review and provide comments on the draft verification report and statement for their technology(ies);
- cover costs associated with the installation and testing of their technology that are above and beyond MERC capabilities and resources (to be specified in individual agreements);
- adhere to all MERC QMP, QAPP and Test Plan requirements.

2.4. Technical Activities Supported by the MERC Quality System

This QMP applies to all BWTS testing performed by MERC. Specifically, it applies to:

- technical activities including planning, testing, and reporting;
- any MERC and MERC-affiliated staff, facilities, and other resources used during testing;
- reference laboratories and collaborators that perform activities in support of testing for MERC.

2.5. Management Assurances of Implementation

MERC is committed to ensuring that the quality system described in this QMP is implemented for its BWTS testing. To ensure that staff understand and implement the quality system requirements:

- all staff involved in ETV testing are required to read this QMP;
- dedicated staff are identified to ensure consistent application of the quality system;
- a QA Manager has been designated with the resources needed to ensure that the QMP is communicated, implementation verified, and that MERC management is apprised of issues requiring corrective action.

2.6. Independence of the QA Manager

The MERC QA Manager is a contracted position, reports directly to the MERC Director, and functions independently of direct BWTS test implementation and data generation responsibilities. The QA Manager has authority to go directly to the MERC Director and find resolution to critical QA problems and

disputes. The QA Manager has sufficient technical, management expertise, and authority to provide independent oversight of and assure the implementation of MERC's quality system.

2.7. Dispute Resolution

Disputes may occur in situations involving technical issues (e.g., audits and data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, quality system reviews, and data usability assessments). If disputes arise during conduct of a test, the Program Coordinator is responsible to resolve the issue with the relevant vendors, reviewers, and/or stakeholders. Every effort will be made to address concerns in a timely manner. If an audit finding or response creates a dispute that cannot be resolved by the QA Manager and/or the Program Coordinator, the dispute will be elevated to the MERC Director for resolution. The MERC Director is the final arbiter of disputes that cannot be otherwise resolved.

3. MERC QUALITY SYSTEM COMPONENTS

The MERC quality system is planned, documented, and implemented to provide management and all vested parties with assurance that test activities are planned and performed in accordance with approved processes and requirements and that MERC test data are credible and reliable. The quality system is described in this QMP and conforms to the specifications listed in:

- ANSI/ASQ E4-2004, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*;
- EPA document: *EPA Requirements for Quality Management Plans*, EPA QA/R-2, March, 2001.

The quality system applies to all MERC activities, including program management; planning; training; BWTS solicitations, application reviews, and selections; BWTS testing and data collection; report approval; and program assessment and improvement.

3.1. Quality System Description

The MERC quality system is comprised of the following components that support the quality policy:

- organization/program quality system documentation, management assessments, systematic planning processes, and training;
- project-specific quality system documentation, and project and data assessments;
- information quality.

3.2. Quality System Tools

For each component used to develop and implement MERC's quality system, MERC applies quality management tools to assist in implementation. Table 1 outlines the components of the MERC quality system, the tools for implementing each component, and responsibilities of management and staff. These tools are described below; additional details of the procedures, requirements, and responsibilities for each are discussed in subsequent sections of the QMP.

3.2.1. Program Quality System Tools

The program quality system tools include documentation and processes that have a strategic focus and broad application across MERC. There are four key tools: quality system documentation; annual reviews and planning; system assessments; and training.

Table 1. Description of MERC Quality System Components and Tools

Quality System Component	Quality System Tool	Description	Roles and Responsibilities
Program Quality System	Quality Management Plan (QMP)	Document describing the quality system including organizational structure, responsibilities and QA assessment.	The QA Manager is responsible for developing and revising the QMP. The MERC Director approves the QMP.
	Quality System Annual Report and Work Plan	A summary of specific implemented QA activities within MERC for the previous calendar year and the planned QA activities for upcoming year.	The report is prepared by the QA Manager with inputs from the senior researchers and technical staff and submitted to the MERC Director.
	Quality System Review/Audit (QSR/QSA).	An evaluation of the integrated quality system implementation (processes). Results are used to improved quality efficiency.	The MERC Director is responsible for initiating evaluations of the quality system effectiveness. The independent evaluation may be done by external evaluators or the QA Manager.
	Training Implementation Plan	Document which identifies (1) specific QA training needs for all levels of management and staff, (2) priorities, (3) strategies, (4) required resources, and (5) the availability of the necessary resources.	The QA Manager is responsible for assessing QA training needs and reporting to the MERC Director.
Project-specific Quality System	Systematic Planning Processes	Planning based on Data Quality Objectives (DQO) process to determine the type, quantity, and quality of data needed to reach defensible decisions on BWTS performance.	The MERC Director is responsible for initiating the development of DQOs.
	Program Quality Assurance Project Plan (QAPP)	An overarching plan that serves as an umbrella under which multiple data collect activities may be conducted over an extended period of time.	The MERC Director and QA Manager develop the Program QAPP with input from senior research and technical personnel.
	Test Plan	The plan developed for each individual test of a technology. The Test Plan provides the experimental approach with clearly stated test objectives and associated quality objectives for the related measurements.	The MERC Director and senior research and technical personnel develop specific Test Plans. The QA Manager develops QA/QC activities with the MERC team.
	Standard Operating Procedures (SOPs)	A set of written instructions that document a routine or repetitive activity that must be performed consistently over time, such as routine sampling, preparation and analytical laboratory methods, instrument service, data management, etc.	MERC Director and senior research personnel develop SOPs; technical staff implements SOPs.
	Field and Laboratory Notebooks, Forms and Records	Documentation of all data and information recorded in support of analytical and process measurements made during planning, testing, and assessing BWTS technology.	Research personnel and technical staff are responsible for maintaining notebooks and records on site, creating electronic copies, archiving.

Quality System Component	Quality System Tool	Description	Roles and Responsibilities
	Technical System Audits (TSA)	A qualitative on-site evaluation of sampling and/or measurement systems associated with a particular BWTS test.	QA Manager responsible for developing assessment methods and conducting TSAs
	Data Quality Assessments (DQA)	Statistical evaluation of data set to determine validity of analytical design and adequacy of data set.	QA Manager responsible for developing assessment methods and conducting DQAs
	Data Verification and Validation	Systematic processes used to evaluate whether data has been generated according to specifications, satisfy acceptance criteria, and are appropriate and consistent with their intended use.	Technical staff performs all data verification and validation, which are then reviewed by the MERC PC.
Information Quality	Internal Review	Procedures to ensure that the informational content of a MERC product is technically sound, meets the project's objectives, and provides an objective analysis of findings.	Research personnel and technical staff prepare the material required to generate an information product. The MERC Director is responsible for the quality of all MERC documents and products.
	Informal External Review	Reviews of documents and information products from qualified individuals who are external to MERC to ensure that the product is technically sound.	The MERC Director or designated senior staff person has the responsibility to coordinate and oversee all external reviews.
	Peer Review	Documented critical review of a specific MERC scientific and/or technical work product by qualified individuals who are independent of MERC.	The MERC Director coordinates and oversees peer reviews.

3.2.1.1. Quality Management Plan

The MERC Quality Management Plan (QMP) is a "living document" which presents a blueprint of the organizational quality system. It covers all aspects of MERC's commitment to quality including policies and procedures; criteria for and areas of application; roles, responsibilities, and authorities; and assessment and response. It is the framework for planning, implementing, documenting, and assessing MERC's QA activities.

The QA Manager is responsible for preparing the QMP and initiating annual reviews, which include input from all end-users of the QMP. The MERC Director reviews drafts of the QMP and proposed revisions. An approved final draft is distributed to MERC senior researchers and technical staff prior to preparation of the final version. The QA Manager also is responsible for ensuring compliance with the QMP and communicating compliance efforts to the MERC Director. Senior research personnel and technical staff are required to follow QMP goals and strategies and are encouraged to actively participate in QMP revisions.

3.2.1.2. Quality System Annual Report and Work Plan

The Quality System Annual Report and Work Plan (QAARWP) is a summary of specific implemented QA activities within MERC for the previous calendar year and the planned QA activities for upcoming year, such as s project-specific audits, assessments and responses; quality system documentation and SOPs; and training. It also includes a discussion on the status of the MERC quality system, including strengths, weaknesses, successes and problems; an assessment of the adequacy of the MERC QMP; and recommendations for improvements. The Annual Report is prepared by the QA Manager with inputs from the senior researchers and technical staff. The report will follow the EPA document *Guidance for Annual Reporting of Quality System Progress*, January, 2008, to the greatest extent possible. The report is initially submitted electronically to MERC Director at the end of each year. The electronic submission is then followed by a hard copy of the signature page signed by the QA Manager.

3.2.1.3. Quality System Process Assessments

Quality system process assessments are conducted by performing a Quality System Review/Audit (QSR/QSA). QSR is a qualitative evaluation of MERC to determine whether the current quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed to evaluate the performance of BWTS are obtained. QSR is a tool used to determine the effectiveness of, and adherence to, the quality system and the adequacy of resources and personnel provided to achieve and ensure quality in all activities. The focus of these assessments is on the quality system process and not on evaluating the quality of specific products or the performance of personnel. Depending on the availability of resources, external QA experts or the QA Manager will perform an independent QSR of MERC's quality system once every three-to-five years. QSR's will follow the EPA document *Quality System Assessment Guidance,* EPA QA/G3, March, 2003, to the greatest extent possible.

3.2.1.4. Quality System Training

Under its quality system, continued training is critical to ensure that all MERC personnel remain proficient in their operational functions and meet QA requirements. Typical quality systems training addresses the policies, processes, procedures, and written instructions related to operational activities.
The MERC training plan describes overall training requirements, training methods, training effectiveness evaluation, training record retention and the periodic review of training. The QAPP and SOPs specify

minimum training requirements. The MERC Program Coordinator and senior research personnel are responsible for ensuring that staff who acquire, generate, compile, or use test data are familiar with quality requirements and for verifying that technical staff members are trained in applicable standard operating procedures and the proper use of sampling and analytical equipment. The PC will maintain a record of all QA training taken by staff responsible for BWTS test data generation. The need for training or retraining to maintain quality-based qualifications is identified by communication with staff, observation of work processes, and QA assessments or audits.

3.2.2. Project-Specific Quality System Tools

At the project level, planning, implementation, and assessment tools are applied to MERC's data generation, acquisition, and use. In the planning phases of a project, MERC applies a systematic planning process (such as the data quality objectives process) to specify performance criteria for data operations. Project-specific quality system tools include documentation and assessments. Three types of documents are used for MERC BWTS testing: (1) the Program QAPP, (2) the Test Plan, and (3) Standard Operating Procedures (SOPs). The Program QAPP is meant to promote uniform testing, and therefore, is a more general document. The Test Plan gives the specific information needed to conduct a test. If another level of detail is required for describing test activities, SOPs are included in the Test Plan. During testing, detailed, systematic records are maintained; and three types of assessments are performed: (1) technical systems audits (TSAs), (2) data quality audits (DQAs), and (3) data verification and validation.

3.2.2.1. Systematic Planning and the Data Quality Objectives Process

MERC uses systematic planning to develop BWTS tests and link goals, cost and schedule, and quality criteria with the final outputs. Systematic planning ensures that all participants understand the needs and expectations of MERC's stakeholders and the product or results to be provided by MERC. MERC uses the EPA document *Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4, February, 2006, as guidance. The Data Quality Objectives (DQO) process is a series of logical steps to establish performance and acceptance criteria (or data quality objectives), which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support defensible decisions about MERC tests of technology performance. Use of the DQO Process leads to efficient and effective expenditure of resources; consensus on test objectives; and the full documentation of actions taken during the development of the test.

3.2.2.2. Program Quality Assurance Project Plan

The MERC Program QAPP provides an overarching plan that describes the quality objectives and documents the general, common activities that are to be conducted at multiple locations or over a long period of time. In contrast to the test-specific QAPP, described below, it serves as an umbrella which describes in a single document the sampling, analysis, QA/QC, data review, and assessment procedures that are not site or time-specific but apply in all MERC tests.

The MERC QA Manager, in conjunction with the Program Coordinator, is responsible for developing the QAPP. The format for both the program and test-specific Test Plans is based on the EPA document *Guidance for Quality Assurance Project Plans*, EPA/QA G-5, December, 2002. The draft Program QAPP is distributed to relevant MERC senior research personnel for review and comment. Once a draft is finalized, the document is then passed on to the MERC Director for review and approval. The Program QAPP is reviewed annually to ensure that its content continues to be valid and applicable to MERC over time.

3.2.2.3. Test Plan

A Test Plan is a technical planning document for a specific MERC test that integrates the contributions and requirements of all MERC personnel involved in the test into a clear, concise statement of what needs to be accomplished, how it shall be done, and by whom. It specifies DQOs, sample collection and field methodologies, laboratory and analytical methods, and the QA and QC associated with all field and laboratory activities. The four Test Plan elements include: (1) project management, (2) measurement/ data acquisition, (3) assessment/oversight, and (4) data validation and usability.

The Program Coordinator and QA Manager are responsible for submitting the Test Plan to the MERC Director for review and approval. It must be submitted to the MERC Director at least 30 days before the start of a test to allow sufficient time for review and revision, if needed. All Test Plans must be reviewed and approved by the MERC Director prior any data gathering work or use.

3.2.2.4. Standard Operating Procedures

It is MERC policy that Standard Operating Procedures (SOPs) are in place for all routine procedures that affect the quality of products or services, such as sample collection, equipment operation, laboratory operations, and data management. The goal of an SOP is to ensure that all personnel perform the procedure consistently over time. SOPs help to ensure the integrity, reproducibility, and quality of data and must be clearly written with sufficient detail that a qualified individual can perform the procedure independently. Procedures that are not routine, or that are unique to a test, may be described in the Test Plan or in written protocols attached to the Test Plan.

SOPs may be developed internally, or may be adopted from approved procedures developed by state and federal agencies or by organizations that develop standards. Internal SOPs are prepared using the EPA Document *Guidance for the Preparation of Standard Operating Procedures*, EPA QA/G-6, April 2007. The source for a SOP must be referenced clearly if it originates from an external source. SOPs should be reviewed by users on an annual basis, updating the document when appropriate.

3.2.2.5. Field and Laboratory Notebooks, Forms and Records

Systematic records must be maintained for each BWTS test. Project records must be detailed enough to track project progress, identify decision points, and support conclusions. Field and laboratory notebooks are the primary source for laboratory and field observations and measurements; sampling details; and instrument and equipment calibration and maintenance information. These books serve as a permanent record of the work. Specific forms are used to record sample collection and analysis data. MERC personnel are responsible for maintaining notebooks on site; ensuring forms are correctly filled out, creating electronic copies of notebooks and forms, and storing and archiving.

3.2.2.6. Technical System Audits

A technical systems audit (TSA) is a qualitative on-site evaluation of sampling and/or measurement systems associated with a specific BWTS test. The objective of the TSA is to assess and document the conformance of on-site testing procedures with the requirements of the QAPP and associated SOPs. The TSA may assess test facilities, equipment maintenance and calibration procedures, reporting requirements, sample collection, analytical activities, and QC procedures.

The MERC QA Manager conducts a TSA at least once during each BWTS test. TSAs are performed following the EPA document *Guidance on Technical Audits and Related Assessments for Environmental*

Data Operations, EPA QA/G-7, January, 2000. A TSA checklist based on the Test Plan is prepared prior to the assessment by the MERC QA Manager and submitted to the MERC Director. Approval of the checklist is not required prior to the TSA, but any comments will be incorporated.

3.2.2.7. Data Quality Assessments

MERC uses Data Quality Assessments (DQAs) to assess the type, quantity, and quality of data generated in order to verify that the planning and project objectives, Test Plan components, and sample collection and analytical procedures were satisfied and that the data are suitable for its intended purpose.
MERC's DQA is a multi-step process, which involves the use of statistical and graphical tools to assess data quality. MERC's DQA process follows the EPA document *Guidance for Data Quality Assessment: Practical Methods for Data Analysis,* EPAQA/G-9, January, 2000.

It is the responsibility of the Program Coordinator and the QA Manager to conduct a DQA after completion of the test.

3.2.2.8. Data Verification and Validation

MERC uses data verification and validation to evaluate whether data has been generated according to specifications, satisfy acceptance criteria, and are appropriate and consistent with their intended use. Data verification is a systematic process for evaluating performance and compliance of a set of data when compared to a set of standards to ascertain its completeness, correctness, and consistency using the methods and criteria defined in the Program QAPP or Test Plans. Data validation follows the data verification process and uses information from the project documentation to ascertain the usability of the data in light of its measurement quality objectives and to ensure that results obtained are scientifically defensible.

The QA Manager is responsible for providing data validation support to MERC. For data verification and data validation, MERC follows the QA and technical specifications of the QAPP and analytical methods, and the procedures set forth in the EPA document *Guidance for Data Verification and Data Validation*, EPAQA/G8, November, 2002.

3.2.3. Information Quality Tools

MERC utilizes various review processes to ensure that the quality of information products is adequate for the intended use and that the content of the information product is technically sound and objective. Staff and management have roles and responsibilities, described below, to ensure that pre-dissemination review procedures are successfully implemented and that the quality of information is known and documented prior to its use. The type and extent of the review depends upon the nature and importance of the information or product. The MERC Director determines the most appropriate level of review.

3.2.3.1. Internal Review

The primary author has the main responsibility to ensure that the informational content of a product is technically sound and meets the project's objectives. The objective of the internal product process is to assist MERC staff in producing quality products that are targeted at the right audience, utilize effective graphics and layout, and deliver a message which will achieve the desired result. The MERC Director has final authority over the quality of all documents and products generated within MERC for public dissemination.

3.2.3.2. Informal External Review

MERC periodically may solicit reviews of documents and information products from qualified individuals who are external to the program. External review is principally to ensure that the product is technically sound. The MERC Director or designated senior staff person has the responsibility to coordinate and oversee all external reviews.

3.2.3.3. Peer Review

Peer review is a documented critical review of a specific MERC scientific and/or technical work product and is generally considered to be the highest level of technical quality review. Peer review is conducted to ensure that activities are technically supportable, competently performed, properly documented, and consistent with established quality criteria. It includes an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work product and of the documentation that supports them.

The MERC Director determines which products shall undergo formal peer review as well as what type of peer review mechanism will be utilized. The MERC Director or designated senior staff person has the responsibility to coordinate and oversee all peer reviews. The Program Coordinator is responsible for maintaining records sufficient to document the review process and outcomes.

4. PERSONNEL QUALIFICATIONS AND TRAINING

4.1. Training Policy

It is MERC policy that staff members have the knowledge, skill, and any professional certifications needed to perform their MERC assignments and that quality management responsibilities and requirements are understood at every stage of project implementation throughout MERC. If formal training is available or required, such training must be documented. The MERC Director is responsible for ensuring adequate resources to support the professional development and training of MERC personnel.

4.2. Processes for Ensuring Qualifications and Training

For MERC, project personnel qualifications and training must be suitable for technical work performed in support of testing activities. The QAPP and SOPs define the specific qualifications required for key personnel and any specialized training. Staff qualifications are assessed as part of the test team assembly. Training and qualification are achieved through formal education, class-time, seminars, and on-the-job training. Training focuses on both the staff members' specific job functions and the related QA system requirements. Staff must have demonstrated ability in an assignment prior to working independently.

Under its quality system, MERC has established a training program that includes the following:

- identification of training needs;
- provision of training to satisfy these needs;
- evaluation of effectiveness of training;
- documentation of training and/or re-training.

4.2.1. Identification of Training Needs

Under MERC's quality system, continued training is critical to ensure that personnel remain proficient in their operational functions and in their understanding of QA requirements. The primary means to assess job proficiency is demonstrated skill as witnessed by a qualified trainer/staff member. Other means for identifying training needs are through QA assessments or audits, and one-to-one discussions among the QA Manager, the Program Coordinator, and staff. Training priorities are jointly developed and negotiated by the QA Manager, the Program Coordinator, and the MERC Director as part of the annual QAARWP development.

4.2.2. Staff Training

MERC's quality systems training addresses the policies, processes, procedures, and written instructions related to operational activities. As noted above, the MERC QAPP and SOPs define the function, responsibilities, authority, dimensions, and requirements for each job title. These criteria establish the minimum requirements for training and demonstration of proficiency for each staff member. Minimum requirements for each job assignment may include professional training, appropriate degrees or years of experience, and demonstrated expertise.

Staff training is primarily accomplished through on-the-job training, seminars, and internal or external training sessions. During on-the-job training, staff performs work under the supervision of qualified personnel. For some activities, such as the use of instruments or equipment, proficiency is demonstrated by the ability to perform instrument inspections, operation, calibration, and maintenance; objective measures such as instrument performance can be used to assess proficiency.

MERC staff has access to other in-house training resources that provide learning in a variety of formats, including web-based, self-paced, training videos, or webinars. Seminars may be offered on-site by MERC for organization-wide requirements and to enhance specific skills. Off-site training, project/program meetings, and technical society membership are available for specific disciplines contributing to the staff member's overall job proficiency.

To ensure that MERC personnel are familiar with current QMP requirements, they will be notified when the QMP is revised and provided with a summary and explanations of the change. The need for retraining will be based on changes in job requirements (assignments), modification of existing procedures, or quality system requirements for periodic refresher courses. Generally, the need for retraining will be determined by the staff member and the appropriate level of management (MERC Program Coordinator, Laboratory Directors). To maintain staff proficiency, opportunities are provided by MERC annually and as needed.

4.2.3. Training Evaluation

It is important to track the quality systems training program's contribution to the organization's mission and goals. The effectiveness of the training is assessed by the supervisor from (1) feedback from the participants and (2) observation of work performance.

4.2.4. Training Documentation

Relevant training that demonstrates staff qualifications to perform the verification test activities must be documented. The MERC Program Coordinator will maintain a record of all training taken by staff and managers in the staff member's qualification/training file. Records should include education history;

work experience; experience in the application of QA/quality control (QC) requirements in technical performance or data verification; on-the-job training in specific skill documented by qualified individuals; and expertise in advanced technical activities based on experience and demonstrated competence.

MERC partner laboratories working on individual BWTS test operations are expected to provide the Program Coordinator with records of educational background and work relevant to technical areas related to the technology undergoing testing. This information will be reviewed by MERC QA Manager during the TSA.

4.2.5. Responsibilities

The Program Coordinator and senior research leaders are responsible for ensuring that personnel who acquire, generate, compile or use test data are familiar with quality requirements and for verifying that technical staff members are trained in applicable standard operating procedures and the proper use of sampling equipment. The Principal Investigators provide staff with training materials and SOPs. Principal Investigators are responsible for ensuring adequate resources for the professional development and training of laboratory personnel. The MERC QA Manager is responsible for arranging for, and assisting in, defining QA/QC training needs on a regular basis to update MERC staff with developing QA/QC issues.

5. PROCUREMENT AND ACCEPTANCE OF ITEMS AND SERVICES

MERC procurement activities may range from general and scientific supplies to highly sophisticated scientific instrumentation and services which directly affect the quality of BWTS testing.

5.1. Procurement Policy

As a unit of UMCES, MERC follows the USM Procurement Policies and Procedures (VIII-3.00) and the University of Maryland (UMCP) Procurement Policies (VIII-3.10A, VIII-3.10B).

5.2. Procurement Documents

Technical and quality requirements for items and services procured for a specific BWTS test are included in the Test Plan. These requirements will typically be specified under materials and/or measurement system equipment (QAPP Section B8, Inspection/Acceptance Requirements for Supplies and Consumables). Procurement technical and quality requirements are generally based upon value (cost, durability, maintainability), performance (specification compliance, operating conditions, calibration capacity), delivery (timeliness, ease of ordering), customer support (responsiveness, technical ability), past experience with a particular vendor, and completeness and coherence of instructions (clarity, accuracy).

The request for items or services is initiated by the Program Coordinator. The Program Coordinator will review purchase orders and contracts for critical supplies and equipment to ensure that they define the level of quality needed. Purchase orders and contracted services must be complete, accurate, and clearly describe, as appropriate:

- the item or service needed;
- any associated technical and quality requirements (such as purity, calibration requirements, etc.);
- quality system elements for which the supplier is responsible, e.g., internal review of analytical results for accuracy;

- how the supplier will verify conformance to MERC's requirements, e.g., internal review of technical activities vs. the QAPP requirements for QC samples.

The MERC Director has final approval over procurement of all items and services.

5.3. Procurement of Items

Specific monitoring, sampling, and analytical equipment are procured only after quality requirements have been discussed among MERC senior research personnel, and when appropriate, the MERC QA Manager. The criteria for selection of the specific items are outlined prior to approval of the procurement. If the items or services will be purchased through an ongoing Price Agreement, the UMD Purchasing Division will issue an Invitation to Bid (ITB) for the items. Depending on the procurement, MERC personnel may participate in the technical evaluation of the responses to the ITB. After technical and administrative review, the State Purchasing Division will issue a Price Agreement for the products that were described in the ITB.

5.4. Procurement of Services

The Program Coordinator ensures that quality control is incorporated within the specific scope of work for each task assignment. Quality assurance for service contracts is based on contractor performance measures which include, but are not limited to, the ability of the contractor to adhere to the contract terms and conditions, and the ability of the contractor to complete the work in accordance with the approved QAPP, Test Plan and/or other work plan.

5.5. Responses to Solicitations

If any aspect of BWTS testing is contracted to another organization, such as an independent reference laboratory, the proposal or qualifications submitted by that organization must be reviewed by the Program Coordinator and MERC Director to ensure that the supplier has a documented quality system consistent with this document and that it has the qualifications to perform the work defined in the QAPP. At a minimum, the Program Coordinator should verify the following:

- documentation of the organization's quality system in a current, detailed quality manual;
- SOPs or protocols exist for the critical aspects of testing (e.g., sample analysis);
- limits of detection and/or quantitation are defined for critical quantitative measurements;
- procedures for equipment and instrument calibration have defined frequencies and acceptance criteria;
- QC samples are defined with frequencies and acceptance criteria;
- methods for independent data verification and validation are defined.

Where possible, compliance to the QAPP should be included as part of the purchasing agreement. Also, laboratory and other services should meet registration or certification requirements applicable to the BWTS test. The laboratory should be provided with pertinent sections of the QAPP or asked to provide input to the analytical sections to ensure that the QAPP accurately reflects laboratory capabilities and practices.

5.6. Acceptance of Purchased Items and Service

Technical personnel must inspect purchased items when received to ensure that they are not defective and that they are of the right type and quality to meet the intended use. Purchased services (e.g., laboratory analysis, subcontractor reports) must be reviewed to ensure that the quality meets the requirements of the project or intended use. If so defined in the Test Plan, a TSA will be conducted during project activities to assess performance in real time.

5.6.1. Test Equipment

Testing equipment procured for activities affecting quality must be calibrated to ensure accuracy with required specifications listed in the QAPP and/or Test Plan and may be verified prior to use in the BWTS test (e.g. PE audits), as appropriate. Any discrepancies shall result in a recalibration of the equipment, or if the equipment is unusable, then a return of the item to the supplier for repair/replacement as necessary. Verification, storage, and maintenance records will be included in individual verification test records.

Technical personnel will test equipment purchased or rented for activities affecting quality. Equipment must be calibrated using independent standards to ensure that the level of accuracy and precision defined in the QAPP can be achieved. Critical equipment performance must be verified prior to use in the BWTS test. If the equipment does not meet QAPP criteria initially, then the equipment should be recalibrated prior to further use. If the equipment is found to operate outside of the QAPP criteria, then it must either be tagged and removed from service or returned to the supplier for repair/replacement, as necessary. Initial verification, routine calibration, and maintenance records will be included in individual BWTS test records.

5.6.2. Testing Materials

Test materials procured for activities affecting quality (e.g. reference standards or gases) should be accompanied with a Certificate of Analysis (COA) where appropriate. The COA will be examined to ensure that the listed specifications are within the QAPP limits. The COA will be retained and included in the BWTS test records.

5.6.3. Services

Methods to accept procurement of services (i.e. subcontractors, installation, repair, or maintenance work, etc.) include technical verification of the data produced, surveillance and/or audit of the activity being performed, or review of objective evidence for conformance to procurement document requirements. Analytical data should be accompanied by a QC narrative that summarizes the analytical results and any QC failures or technical deviations from the laboratory SOPs, QAPP, or Test Plan.

5.7. Other Agreements

MERC may utilize other types of governmental agreements, such as Memorandum of Understanding or Memorandum of Agreement (MOU or MOA) with other international, Federal, State, and local agencies or organizations. A MOU may be used to share resources that mutually benefit the agencies and/or public. A MOA may be used to fund specific projects that benefit two agencies. These agreements do not go through the procurement process.

MERC maintains an agreement for analytical services with CBL/UMCES Nutrient Analytical Services Laboratory (NASL). MERC and NASL communicate their requirements through annual negotiations and interim meetings.

Participation agreements are used to establish relationships between MERC and ballast treatment developers that would like to receive MERC testing services. In this situation, non-disclosure agreements may also be drafted between the parties. Example of a MERC and vendor agreement is provided as Appendix B.

6. DOCUMENTS AND RECORDS

MERC has established procedures for maintaining and controlling documents and records. The MERC Director is responsible for developing, approving, and communicating these procedures and processes to users.

6.1. Quality Management Documents

ANSI/ASQ E4-2004 states that documents may be any media that contains information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. Quality management documents consist of policy statements, operating procedures, and work instructions needed to control work processes and outcomes.

6.1.1. Controlled Documents

Some documents require control to ensure that the most current versions are available to document users. Quality-related documents requiring control include:

- QMP for MERC;
- Standard Operating Procedures (SOPs);
- Program QAPP and Test/QA Plans, including amendments and deviations;
- Technical System Audits;
- Data Audits.

Document control is maintained by implementing the following steps:

- Formal signature approval block within the document (QMP and SOPs, only);
- An effective date;
- A specific version number or designation as a permanent part of the document;
- Retention of the document with original signed page(s) in a limited access storage area (QMP, QAPP, Test Plans, and SOPs);
- Notification of document publication or revision as MERC announcement and email to applicable distribution list (QMP and SOPs, only);
- Availability of only the current version of each document on the MERC web site;
- Revision only by the originator/author of the document or as assigned by the MERC Director.

Controlled document identification will be assigned by the person primarily responsible for the document (typically the originator/author). The MERC Director will maintain a distribution list for the QMP and any program or project-specific SOPs and is responsible for ensuring that these individuals are notified if the documents are updated. The Program Coordinator has this responsibility for the QAPP and Test Plans, amendments, and deviations. The current, approved versions of the documents are made available on the

MERC web site. Printed copies are considered uncontrolled and the version noted in a printed copy should be checked against the web site document prior to use. MERC staff maintains quality documents for historical and legal purposes as required and dispose of superseded, obsolete documents. Discontinued materials and superseded documents are retained in the archives for at least three years.

6.1.2. Confidential Documents

Some documents collected, received, or generated may, by nature and content, be documents which require special handling procedures. Documents of this category may be, but are not limited to, confidential business information. Vendor technology information marked proprietary must not be disclosed, intentionally or unintentionally, to anyone except other authorized relevant MERC staff. Appropriate markings are to be used on all sensitive materials to assist in their protection. Confidential documents shall be maintained separately from other QA documents.

6.2. Records

ANSI/ASQ E4-2004 states that a record is a document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media. Typical MERC records include test project files and test records.

6.2.1. Test Project Files

Detailed, systematic records must be maintained for each MERC test. Project records shall be detailed enough to track project progress, identify decision points, and support conclusions. Project data and records must be capable of withstanding challenges to their validity, accuracy, and legibility. The PC is responsible for meeting these requirements at a minimum:

- Hard copy documents and records that are part of the project study files should be maintained in organized project files.
- Electronic project study files must be maintained on the MERC Web site; no project files may exist only on personal computers.
- The PC is responsible for setting up the project folder with main folders and subfolders needed to effectively manage project records. At a minimum, the project folder should contain folders for project management records, work in progress, data, draft or pre-delivery reviews, and final deliverables.
- The Test Plan will specify the specific project file locations and requirements.
- The PC has the option of setting up external sites for data sharing with other project collaborators.

6.2.2. Test Data Records

Data collected in support of MERC testing must be collected using scientifically valid methods and retained securely. The PC is responsible for meeting these requirements at a minimum:

- Raw (original) data collected in the field or laboratory should be recorded such that samples collected and data generated are complete and traceable throughout their history. (Note: Raw data are defined as any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, computer printouts, magnetic media, including

dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data verified accurate by signature), the exact copy or exact transcript may be submitted.)

- Data should be recorded in standardized formats, e.g., data collection forms, bound and paginated laboratory and field logbooks, laboratory record books, spreadsheets, computer records, and output from instruments (both electronic and hardcopy). The QAPP must define how test data will be documented.
- All test records shall carry minimum identification pertaining to title, responsible person or author, and date.
- All manual entries shall be entered using ink and initial and dated by the individual recording the entry.
- Changes to original (raw) data should not obliterate the original entry and should be corrected using a single line and annotated with the new data, and the date/initials of the person who modified the record. A short explanation will be added to non-obvious corrections.
- Electronic data collected by field or laboratory instruments should be backed up daily or transcribed daily onto a hard copy data form and verified 100% by another person.
- Instrument logs should be used document use and maintenance. Calibration records should be maintained as part of the test project file.
- Laboratory and field records must be completed, reviewed in real time, and provided to the PC as soon as practically possible.
- Once a test has been completed, the PC must complete a MERC TEST Project Closeout list when sending project test files for archiving.

6.2.3. Sample Documentation

It is critical that documentation prior to, during, and after field operations should be adequate to enable historical reconstruction of all events resulting in final data, including sufficient detail so that decision logic may be traced. Unique sample numbers and rigorous sample transfer procedures are critical to data traceability.

6.2.3.1. Sample Identification Numbers

Unique sample numbers must be assigned to each collected sample to enable sample tracking through an entire process to ensure samples are not switched accidentally, lost, or reported with the wrong data.

6.2.3.2. Sample Custody

When samples are transported from the field, regardless of transportation method, a sample transmittal or chain-of-custody (COC) form must accompany the samples. The form should list each sample present in the shipping container. Samples are considered to be in a person's custody if:

- The samples are in a person's actual possession.
- The samples are in a person's view after being in that person's possession.
- The samples were in a person's possession and then were locked or sealed up to prevent tampering.
- The samples are in a secure area.

6.3. Maintaining Document Version Control

It is important that version control be maintained for project documents and records, including data spreadsheets. Thus, MERC utilizes a naming convention that uniquely identifies each document revision as follows:

- Internal working document versions are named with the file name and the date updated.
- Review versions are re-named by adding the initials of each reviewer to the document.
- When a document is ready for release outside of MERC, it is renamed as either draft, final, or revised final with the date of release. Initials and internal naming conventions are removed
- Internal revisions in response to comments are named logically using the format above to again track changes through the revision process.

6.4. Compliance with Records and Documents

Testing performed by MERC must conform to the QMP, Program QAPP, Test Plan and applicable SOPs. A deviation occurs when testing does not comply with the requirements of these documents. Once a deviation has been identified during testing, it must be communicated to the MERC Director and Quality Manager within 24 hours and documented in a formal deviation. Deviations must be fully documented including, date and description of deviation, and impact on the test.

6.5. Document and Records Management

All MERC documents and records used to administer this QMP and needed to reconstruct test activities and verify that reported data were collected in a manner consistent with this QMP and MERC requirements are managed throughout a four-stage life cycle: creation, active maintenance and use, archiving, and disposition. The life cycle is initiated by the creation, collection, or receipt of records in the form of data or documents in the course of carrying out MERC's administrative and programmatic responsibilities. The life cycle continues through the processing and active use of the information in the record, until the record is determined to be inactive. Electronic records are archived on write-protected, secure electronic media following accepted data management practices. Metadata should accompany data archives. Metadata should include the data format, data fields with associated units, and other information intended to inform the data user about the nature of the data, their quality, or their use. A duplicate copy of the data archive must be stored in a secure, off-site location. Program files and QA records will be maintained for 5 years. The final step in the life cycles is disposition. Disposal procedures for documents and records that are no longer required after 5 years include electronic deletion of documents and records from the MERC website and the personal computers of MERC personnel and manual shredding of hard copies.

6.6. Compliance

The MERC QMP, QAPP, and Test Plans are prepared to meet the format and content requirements of EPA QA/R-2 (2001), and EPA QA/R-5 (2002), respectively. Approval of these documents by MERC Director, QA Manager and/or designee establishes compliance.

6.7. Document Distribution

Once documents and records have been reviewed and approved as required, distribution will be made as listed in Table 2.

Table 2. Document and Records Management Responsibilities for MERC

Record Type	Preparation/ Updating	Review	Approval	Finals Distributed to:
Cooperative Agreement Reporting Records (e.g. annual progress reports)	MERC Director	MERC Program Coordinator		• MARAD Project Officer • Maryland Port Authority
MERC Quality Management Plan	MERC QA Manager	MERC Director	• MARAD Project Officer • MERC Director	• MERC Research Personnel and Technical Staff • MARAD Project Officer • Maryland Port Authority
QAPP (including SOPs, amendments, deviations)	MERC Program Coordinator	MERC QA Manager	MERC Director	• MERC Research Personnel and Technical Staff • MARAD Project Officer • Maryland Port Authority
BWTS Test Plans	MERC Program Coordinator	MERC QA Manager Developers/vendors	MERC Director	• MERC Research Personnel and Technical Staff • MARAD Project Officer • Maryland Port Authority
BWTS Test Raw Data	MERC Research and Technical Personnel	MERC Program Coordinator, QA Manager, and Data Manager	MERC Director	MERC project files
BWTS Test Report	MERC Program Coordinator and Data Manager	MERC QA Manager and Director Developers/vendors	MERC Director	Post to MERC web site
BWTS Test Audit Reports	MERC QA Manager	MERC Director MERC Program Coordinator	MERC Director	MERC Project Files

7. COMPUTER HARDWARE AND SOFTWARE

7.1. General Procedures

Computer software and computer hardware configurations used in MERC must be installed/tested/used/maintained/controlled/documented to meet BWTS testing' requirements and will conform to this quality policy and applicable consensus standards and/or data management criteria. Hardware and software capability needs are assessed during the planning process, and specific needs are defined in the QAPP and/or Test Plan. The selection and use of hardware and software must conform to the requirements of UMD. At the program level, MERC does not expect to develop software. Software that may be developed in support of specific BWTS testing will follow procedures specified in the MERC QMP (this document).

In general, it is the responsibility of the individual MERC Partner Laboratories to maintain computer hardware and software utilized for MERC. The following are the MERC procedures which ensure that each Partner organization controls the quality of all computer hardware/software configurations for the program:

- the MERC Director and the senior researcher at each MERC Partner institution discuss and agree upon the computer hardware and software requirements for the program and/or for specific test/QA plans;
- once decisions are finalized, the MERC Partner organization supplies evidence of meeting all requirements before data collection, reduction, or validation procedures begins;
- for new software developed for BWTS testing, the MERC Partner organization tests all applications and configurations using a test data set or by running a shakedown test of the system to ensure all applications/configurations are operating to specifications. The MERC Partner organization must show evidence of a system to maintain, control, and document such software and hardware configurations. This includes, but is not exclusive of: resources to correct any hardware/software failure with minimal downtime to the program, tracking upgrades/revisions to software or configuration changes, documenting software names, versions, and copyright dates, and complete documentation of the code. Complete documentation of code includes the written code with comments structured in a modular form.

7.2. Hardware

Computer hardware will be maintained to manufacturers' standards and upgraded as needed to improve performance and provide complete compatibility with current standards or program requirements. The decision to upgrade computer hardware is based on an assessment of test needs, current capabilities, and the impact or upgrading hardware on data accessibility.

7.3. Software

Each computer at MERC is set up with standard complement of software. The need for other, specialized software to support a BWTS test will be identified in the QAPP and/or Test Plan. Most software used at MERC is acquired commercially, loaded, and tested as specified by the publisher. Software used for data management activities may include Microsoft Excel, Access, FileMaker, MATLAB and/or CAD. Standard word processing software (e.g. Word and Adobe) is used to create reports. MERC uses software patch management and software version upgrade processes to ensure that the baseline software is kept up-to-date with the latest security patches and upgrades.

7.4. Change Control

Change control involves tracking software and hardware versions used for specific data collection and management activities so that data can be reproduced using the version used to create it (e.g., instrument software versions) and so that if problems or "bugs" are identified in specific hardware or software versions, the affected data can be identified and fixed. MERC tracks the hardware configuration and software versions loaded on each PC during set-up.

The purpose of retesting and recalibration is to verify that a new system is compatible with the previous system and that it will accommodate previous data entry and data reduction programs without impact to formats and output are not changed. For more complex applications, a data set may be re-entered, tested, or plotted and the outputs compared. In these cases, testing results should be documented in the project files. The performance of hardware and software may require retesting if:

- Hardware components are changed.
- Software configuration is modified.
- New or updated software is installed.

The Program Coordinator and Facility Manager must be aware of hardware and software change control and potential impacts of version differences. They are responsible for determining if and how retesting is required and how retesting will be accomplished and documented.

7.5. Purchased Hardware and Software

Any specialized hardware or software purchased for a specific MERC application must be evaluated to ensure that it meets the intended use requirements and that it complies with any contractual requirements and standards. The evaluation process will be defined in the QAPP and/or documented in the project files.

7.6. Validation Policy

Since nearly all hardware and software used for MERC is commercially available, wide public use and continued market viability is considered proof of software dependability; therefore, validation is not considered necessary. However, verification of data analysis techniques within each program is required. For example, spreadsheet formulas and output shall be independently reviewed, verified, and documented.

7.7. Roles and Responsibilities

The Information Resources offices of the MERC Partner institutions have the primary responsibility for setting policy and guidance for the management and development of computer-related program support for MERC These offices are responsible for their respective institution's Local Area Network, database management, information security, personal computing and information access, application development, desktop support, training, and records management.

8. PLANNING

Systematic, timely, and effective planning is necessary to assure that data and information collected for MERC BWTS testing meet the objectives and quality for their intended use.

8.1. MERC Systematic Planning

MERC has established and implements a systematic planning process to:

- solicit BWTS technologies for testing;
- review application forms (see Appendix C) and supporting technical information from applicants
- identify the technical and quality goals;
- translate the technical and quality goals into specifications that will produce the desired result;
- consider any cost and schedule constraints within which test activities are required to be performed;
- identify acceptance criteria for the results or measures of performance by which the results will be evaluated.

This planning process establishes the framework to define requirements for testing QA/QC, data collection, and data analysis and evaluation.

8.1.1. Stakeholders

MERC may establish stakeholder committee(s) or technical panels beyond the Advisory Board with representatives of appropriate technology interest groups. Individual stakeholders are selected for these committee(s) based on their expertise and interest in BWTS and their availability and willingness to participate.

A joint meeting of the stakeholder committee or technical panel generally may be held annually, with meetings minutes recorded, reviewed, and circulated to the stakeholders and program sponsors. The meeting can be conducted in person or by teleconference. The purposes of the stakeholder or technical panel meetings include:

- identify, revise, and/or clarify the technical and quality goals of the work to be accomplished;
- evaluate customer satisfaction;
- determine testing priorities;
- discuss test design;
- define and review BWTS test plans;
- consider any cost and schedule constraints within which test activities are required to be performed;
- identify test collaborators;

8.1.2. Planning Personnel

BWTS test planning shall be coordinated by MERC among the participating organizations including the stakeholders, the vendors, and any testing organizations and laboratories participating in the test. MERC will define the planning roles of the participants, and will conduct planning activities by shared communication via e-mail, teleconference, video conference, and in-person meetings, as appropriate, and within the constraints of budget

8.2. Systematic Planning of BWTS Tests

The MERC planning process (Figure 2) will establish the BWTS test details, including:

- goals, data quality objectives, and data quality indicators;
- project schedule, resource needs, milestones, and requirements;
- type and quantity of data needed and how the data will be used to support the data quality objectives;
- data quality performance criteria;
- QA/QC activities to assess the quality performance criteria;
- data collection methods and logistics;
- data analysis and evaluation procedures.

8.2.1. Technical and Quality Goals

The purpose of MERC testing is to evaluate the performance of BWTS. MERC customers require reliable and objective analytical data. These data must have:

- a justifiable approach to selecting analytical procedures and detection limits;
- adequate detection limits and uncertainties;
- well documented QA/QC and analytical procedures;
- document control and accountability;
- adherence to standard protocols and procedures;
- cost-effective testing which provides efficient and timely results.

8.2.2. Cost and Schedule Requirements

The MERC Director, in coordination with test participants, determines cost and schedule requirements relative to technical goals. MERC utilizes the Critical Path Method for test scheduling and control. A project network is constructed, which shows the interrelationships between project activities, establishes the sequence of events, and provides the timelines that these activities and events are to be performed. It identifies the starting and completion time of each activity and establishes how and when available resources are to be allocated among test participants.

8.2.3. Data Specifications

8.2.3.1. Data Quality Objectives

The design process for BWTS testing establishes the test data quality objectives (DQOs). These ensure that the collected data are of sufficient type, quality, and quantity to answer the study questions (typically expressed relative to the ability to estimate an unknown parameter within specified bounds or make a correct decision within a certain degree of confidence).

Once the DQOs are established, the experimental design will be developed. The QAPP will define the test to be conducted, the baseline parameters, the number of replicate tests, and the controls.

8.2.3.2. Data Quality Indicators

Data quality indicators (DQIs) will be defined in the QAPP for each test objective. DQIs are a set of measurable characteristics that address the quality of data at the field and lab analytical level, typically precision, accuracy, representativeness, comparability, and completeness. DQIs have some influence on determining whether the DQOs have been met, as they help define the level of quality in the data. The QAPP must define the DQIs appropriate for the BWTS test objectives and the measurement quality objectives (MQOs; the actual acceptance criteria) placed on the DQIs. The MQOs will be used during data assessment to determine whether the quality of a data set is acceptable relative to the DQIs. Table 3 illustrates the relationship between DQOs, DQIs, and MQOs. Appendix D provides definitions of DQIs and the types of QC samples used to measures them.

The test objectives and DQIs will establish the criteria for the selection of field and laboratory procedures, methods, and equipment. DQIs are defined in MERC QAPPs for reference data as well as for ancillary measurements that support verification test data when possible. DQIs are typically not required in for vendor technology data, since the vendor is responsible for specifying the quality measurements to be made to ensure the integrity of their technology's outputs.

Considerations include reliability under the intended field conditions or sample matrices, detection limits, specificity, and sensitivity. For all test activities critical to the achievement of the DQOs, the QAPP will detail:

- equipment for each field activity and measurement;
- analytical methods for each laboratory procedure;
- sampling and data collection procedures;
- calibration, operation, and maintenance requirements;
- QC samples and procedures to be implemented in the field and laboratory and MQOs for each DQI.

Whenever possible these details should be described in SOPs that are developed by the sampling and testing team or reference laboratory.

Table 3. The Relationship between DQOs, DQIs, and MQOs

Data Quality Objective (DQO) →	Data Quality Indicator (DQI) →	Measurement Quality Objective (MQO)
Qualitative and quantitative study objectives • How 'good' does the study data have to be? • How many samples are needed to determine	Quantitative: • Precision • Accuracy • Sensitivity Qualitative: • Representativeness • Comparability • Completeness	Project specific acceptance criteria for the DQIs
E.g., • 50 samples are needed to achieve desired level of confidence (±30%) that the attribute is correctly characterized	E.g., • Precision • Accuracy	E.g., • Laboratory duplicates precision < 10% RPD • Blank spike accuracy ±15%

8.3. Quality Assurance Project Plans

The core documentation for quality planning of MERC tests are the Program Quality Assurance Project Plan and the Test/ Plan. The Program QAPP is meant to promote uniform testing for all MERC tests and is therefore considered a more general document. The Test plan is prepared for each BWTS test and contains the specific information needed to conduct the test.

The QAPP format and content is based on the EPA document *Requirements for Quality Assurance Project Plans*, EPA QA/R-5, 2001. Elements of the QAPP are defined in Appendix E.

8.3.1. Program Quality Assurance Project Plan

The Program Quality Assurance Project Plan (QAPP) provides the necessary framework for development of the more detailed test/QA plan. The QAPP typically includes:

- general description of MERC;
- responsibilities of all involved organizations;
- experimental design;
- equipment capabilities and description;
- description and use of field test sites;
- description and use of laboratory test sites;
- DQOs for BWTS tests;
- QA/QC procedures;
- Use of existing data;
- data handling;
- requirements for other documents;
- health and safety;
- references.

The QA/QC section of the QAPP typically describes the activities that verify the quality and consistency of the work and provides data quality descriptors, such as accuracy, precision, representativeness, completeness, comparability, and detection limit, as appropriate. Preparation and use of appropriate QA procedures such as QC samples, blanks, split and spiked samples, and PEA samples to verify performance of the technology being tested can be described. Frequency of calibrations and QC checks and the rationale for them can be described. Procedures for reporting QC data and results can be given. Who is responsible for each QA activity, and who has the responsibility for identifying and taking corrective action can be specified. However, if these items vary between tests, the more appropriate document in which to describe them may be the Test plan.

The QAPP may cite documents or procedures that explain, extend, and/or enhance the QAPP, such as related procedures, the published literature, or methods manuals.

8.3.2. Test Plan

The planning process considers selection of test parameters, availability of test equipment, availability of testing personnel, optimal test procedures, and the necessary and sufficient data quality indicators for test measurements. The test design takes into account constraints of time, scheduling, and resources. The product of the design process is a Test Plan, which has the following characteristics:

- documents the process and assumptions used for planning, as well as those persons responsible for the planning;
- specifies the field and laboratory tests to be conducted, the baseline parameters, the number of replicate tests, and the controls;
- specifies field and laboratory equipment and optimal operating parameters;
- specifies sampling methods, sample types, numbers, quantities, handling, packaging, shipping, and custody if the testing involves samples; specifies sample locations, storage conditions, and holding times;
- incorporates analysis methods, quantitative measures of performance, calibration standards, calibration check standards, and performance evaluation samples, as appropriate and as identified in the planning process;
- establishes QC check acceptance criteria to ensure attainment of DQOs; -includes methods and procedures to ensure the test produces data of known and acceptable quality;
- incorporates any other field or laboratory QA/QC activities identified by planners;
- specifies the requirements for qualifications of technical staff responsible for obtaining, analyzing, and evaluating the data;
- incorporates protection of the health and safety of testing personnel and the public;
- incorporates procedures for the minimization and disposal of generated wastes.

The QAPP is incorporated into the Test Plan by reference.

8.3.3. Conformance to the QAPP

All BWTS test activities must conform to the requirements of the Test Plan. Changes to the approved Test Plan that are made before testing begins, or between rounds or phases of testing, must be documented as amendments to the Test Plan. Changes to the approved Test Plan that are made during the test are documented as deviations. Significant changes to the Test Plan may warrant a reversion of the Test Plan. The MERC QA Manager makes the determination as to whether the changes are significant. Revisions are reviewed and approved by the MERC Director. Generation of BWTS test data will not be initiated until the approved Test Plan is in place.

8.4. Existing Data

Existing data are defined as data from databases, data resulting from previous projects, the scientific literature, or other sources. Existing data that will be used for informational purposes to support development of the test design do not require stringent QA requirements. If existing data are to be used as test data for an MERC BWTS test, a more robust data quality assessment will be needed and may require the following documents associated with the data: chain of custody, QC Narrative or Data Validation Report, QA/QC report and laboratory analytical data report.

8.5. Roles and Responsibilities

The MERC Director is responsible for directing all test activities. The MERC QA Manager is responsible for developing and maintaining the MERC QMP (this document). The MERC Program Coordinator and Data Manager are responsible for preparation of the QAPP, amendments, and deviations in compliance with the MERC QMP. The QAPP, Test Plans, amendments, and deviations are reviewed and approved by the MERC Director and QA Manager.

9. IMPLEMENTATION OF WORK PROCESSES

9.1. Compliance with Approved Planning and Technical Documents

MERC BWTS performance evaluations are implemented according to the Test/QA Plans and technical documents (e.g., Standard Operating Procedures) prepared during planning. A kick-off meeting will be held prior to the start of each test to review procedures for the test with all testing staff. Test personnel have access to the approved planning documents, approved changes to planning documents, and all referenced documents. When a prescribed sequence for the work is defined during the planning stages, work performed shall follow that sequence. Changes to that sequence need to be documented by either amendment (planned changes) or deviation (unplanned changes). All staff will be notified of the change, and appropriate action will be taken to ensure that obsolete or superseded procedures are identified and removed from use. All implementation activities are documented. Suitable documents are bound notebooks (e.g. laboratory record books, or LRBs), field and laboratory data sheets, spreadsheets, computer records, and output from instruments (both electronic and hardcopy). All documentation is implemented as described in the planning documents. All implementation activities are traceable to the planning documents and traceable to test personnel.

9.2. Special Procedures

The QAPP, Test Plan, and referenced technical documents must define the procedures for BWTS testing. The level of detail must be adequate for a qualified individual to perform the procedure independently. In some cases, the level of detail needed to adequately describe a procedure is best documented in a specialized, detailed SOP or protocol.

An SOP is developed if the procedure is routine. SOPs are controlled documents and formally approved and tracked. If the procedure is test-specific then a protocol is adequate. Protocols are test-specific documents prepared by the senior research personnel, the Program Coordinator, or the QA Manager. Protocols must be version-controlled in some manner.

A special procedure requiring a detailed SOP or protocol is required if the procedure:

- is complex, involves many steps, and must be completed follow a regime of timing and sequences (e.g., analytical methods);
- is lengthy and is best captured in a separate document;
- involves the quantitative preparation of chemical solutions that impact data quality (e.g., calibration solutions);
- involves the setup, use, and operation of complex equipment or instruments that will impact data quality and that are not easily operated by following simple manufacturer instructions (analytical instruments).

The Program Coordinator is responsible for operations that need written procedures/SOPs, and for preparing, updating, approving, withdrawing, and archiving procedures. The QA Manager is responsible for ensuring that all technical procedures described in the QAPP and/or Test Plan are adequately described in a written procedure.

9.3. Document Control

It is critical that test personnel have access to the current, approved versions of each document required for BWTS testing and that obsolete documents are not available for inadvertent use. MERC's procedures to ensure test-specific document control include the following:

- The final, approved QAPP and Test Plan are distributed to test participants prior to testing.
- Instrument manuals will be maintained with the instruments.
- The QAPP, Test Plans, amendments, and deviations (must be physically available at each site involved in testing.
- SOPs or protocols developed for testing will be distributed to personnel who will be conducting the procedures.

When a QAPP, Test Plan, amendment, deviation (that describes QAPP or Test Plan changes to be implemented), manual, SOP, or protocol is revised, it will be formally distributed to each test participant. Test participants are responsible for immediately removing previous document versions from their work area or saving them in the project files as a historical record. The Program Coordinator is responsible for maintaining all versions of all test documents to maintain a history of project activities.

10. ASSESSMENT AND RESPONSE

All technology evaluation activities require a mechanism for monitoring the effectiveness and adequacy of the QA measures integrated into the program. Assessment and response elements include assigning appropriate, qualified persons to conduct assessments at planned, scheduled intervals; having provisions for timely responses and implementation of corrective actions if needed; and completing the evaluation process with written reports to technical and management staff.

MERC assessments are planned, scheduled, conducted, reported, and tracked to closure by the MERC QA Manager. MERC utilizes assessments to determine both the suitability and effectiveness of the overall quality system and the quality of the testing performed for each BWTS test. The standard oversight mechanisms include: (1) quality system assessment review/audits; (2) technical assessment review/audits; (3) data verification and validation; and (4) data assessment. Each type of review follows, as appropriate, the planning, implementation and evaluation procedures described in the EPA documents:

- *Guidance on Technical Audits and Related Assessments for Environmental Data Operations*, EPA QA/G-7, January, 2000;
- *Guidance on Assessing Quality Systems* EPA QA/G-3, March 2003;
- *Guidance on Environmental Data Verification and Data Validation*, EPA QA/ G-8, January 2008;
- *Data Quality Assessment, A Reviewer's Guide*, EPA QA/G9R, February 2006;
- *Data Quality Assessment; Statistical Methods for Practitioners*, EPA QA/ G9S, February 2006;
- the 2003 NELAC Standard, EPA/600/R04-003.

Overall, the outcome of an assessment is expected to: (1) identify strengths and weaknesses, (2) cause corrective actions to be taken to alleviate problems, (3) facilitate the initiation of changes to enhance the QA program, (4) serve as a vehicle for providing technical assistance, (5) enhance awareness and understanding of QA/QC policies and procedures; and (6) provide a measurement of the effectiveness of QC in assuring the quality of data.

10.1. Quality System Assessment

The MERC Director and MERC QA Manager assess the adequacy of the quality system formally during the annual review and update of the QMP. As part of the review, they consider elements that are adequate to achieve quality results, problems that need further control, and requirements that are obsolete or superseded with other requirements. Systematic issues that require modification to procedures and lessons learned are communicated to the MERC team.

10.2. Quality Assessment Procedures

10.2.1. General Requirements

Fundamental principles of the MERC assessment and response process include:

- Each assessment must be fully documented. The MERC QA Manager will archive all assessment reports generated on MERC.
- Each assessment must be responded to by the appropriate level of the MERC team. MERC quality assessment reports require a written response by the person performing the inspected activity, and acknowledgment of the assessment by the MERC Director.
- Corrective action must be documented and approved on the original assessment report, with detailed narrative in response to the assessor's finding. Initials and date are required for each corrective action response. Acknowledgment of the response will be provided by the MERC Director.
- Implementation of corrective actions must be verified by the MERC QA Manager to ensure that corrective actions are adequate and have been completed. This will be done in real-time if corrective actions can be immediately performed and signed off on the assessment report.

10.2.2. Assessment Planning

Assessment planning is performed by MERC's Director and QA Manager prior to the actual performance of any assessments. Planning the assessment scope helps provide the type of evaluation information needed to determine whether procedural compliance and technical requirements are being met during BWTS testing. Assessment planning by MERC includes a kickoff meeting with the testing team where at least the following information may be discussed:

- schedule of assessment(s);
- proper completion of data records;
- notification to affected parties;
- specific assessment requirements (personnel lists, equipment lists, and availability of Test Plans);
- follow-up procedures for corrective action, including debriefing and discussion of possible resolutions;
- corrective action guidelines to facilitate completion of the reported assessment;
- appropriate management signature approval of the reviewed assessment report.

10.2.3. Types of Assessments

MERC employs several QA assessment tools designed to provide a better understanding of the components of, and basis for improving, the MERC Quality Management System (Table 4). Internal (programmatic) and external QA audits are one of the principal tools for determining the effectiveness of the MERC QA/QC components. QA audit frequency and scheduling will vary with the type of review conducted. Specifics of frequency and type of review will be outlined in the QAPP and/or individual Test Plans.

Table 4. MERC QA Assessments

Assessment Type	Assessors	Document Reference	Reason for Assessment	Minimum Frequency
Performance Evaluation	Program Coordinator, QA Manager,	QAPP, SOPs, Test Plans	Assess measurement performance	Each test as applicable
Technical System Audit	QA Manager	QAPP, Test/ Plans	Assess technical quality of BWTS test	Once per test.
Audit of Data Quality	QA Manager	Raw data and data summary	Assess data calculations and reporting	At least 10% of test data
Data Quality Assessment	QA Manager	QAPP, SOPs, Test Plans	Assess instrument accuracy and precision	QC tests equal to 10% of samples
Data Validation and Verification	QA Manager	Raw data and data summary	Assess compliance of dataset with DQOs and analytical quality of dataset	Once per test

The following is a description of some of the evaluation tools:

10.2.3.1. Performance Evaluation Audits

Performance evaluation (PE) audits are quantitative evaluations used to assess the ability of a laboratory, or field measurement system, to provide reliable data. PE audits should be conducted whenever a reference method is available or whenever a technology will measure a parameter for which a reference sample is available. PEs samples will be considered for all laboratories providing analytical services, directly or indirectly, for MERC and will be traceable, whenever possible, through the National Institute of Standards and Technology (NIST). The evaluation consists of providing a reference, "blind" or “double blind” sample, to the laboratory for analysis. A PE sample contains known concentrations the chemical or biological analyte of interest and will normally be in the appropriate media (e.g., water, sediment). The analytical results obtained by the laboratory are compared to the known concentrations of the analyte contained in the PE sample(s), as a means of determining if the laboratory demonstrated its ability to properly identify, and quantify, an analyte within established, or calculated, control limits.

The type and frequency of PE audits to be performed are specified in the QAPP and/or Test Plan for each BWTS test. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. The MERC QA Manager will review results of PE audits.

10.2.3.2. Technical System Audits

A Technical System Audit (TSA) is a qualitative on-site evaluation of sampling and/or measurement systems associated with a particular BWTS test. The objective of the TSA is to assess and document the conformance of on- site testing procedures with the requirements of the QAPP, Test Plan, and associated SOPs. The TSA may assess test facilities, equipment maintenance and calibration procedures, reporting requirements, sample collection, analytical activities, and QC procedures. Both laboratory and field TSAs may be performed.

The MERC QA Manager conducts a TSA at least once during each BWTS test. A TSA checklist based on the QAPP and Test Plan is prepared by the MERC QA Manager prior to the assessment and reviewed by the MERC Director. For each TSA, TSA kickoff meeting will be conducted with the MERC testing team when possible and appropriate so that the team understands the assessment logistics. The meeting will cover at least the following information:

- schedule of assessment(s);
- proper completion of data records;
- notification to affected parties;
- specific assessment requirements (personnel lists, equipment lists, and availability of QAPPs);
- follow-up procedures for corrective action, including debriefing and discussion of possible resolutions;
- corrective action guidelines to facilitate completion of the reported assessment.

At the close of the TSA, an immediate informal debriefing will be conducted. A formal debriefing by the MERC QA Manager to the MERC Director, MERC Program Coordinator, and the on-site team that was audited, may be conducted when appropriate. The results of TSAs will be documented in a formal audit report. The TSA report schedule is as follows:

- The draft TSA report with the completed checklist will be submitted to the MERC Program Coordinator within 10 days of the TSA.
- The MERC Program Coordinator's audit response is due 10 working days from delivery of the TSA report.
- The final TSA, with audit responses, is due to the MERC Director within 10 days of receiving the response.

The final report with the MERC Program Coordinator's responses accepted by the QA Manager and approved by the MERC Director will be signed, scanned, and uploaded to the MERC documents and records archive.

10.2.3.3. Audit of Data Quality

An Audit of Data Quality (ADQ) is a quantitative evaluation of the BWTS test data. The objective of the ADQ is to determine if the test data were collected according to the requirements of the QAPP, Test Plan, and associated SOPs. The ADQ assesses data accuracy, completeness, quality, and traceability.

The ADQ is conducted after data have been 100% verified by the MERC Program Coordinator or designated project personnel. The MERC QA Manager conducts the ADQ. An ADQ checklist based on the QAPP and Test Plan is prepared prior to the assessment by the MERC QA Manager. The amount of data reviewed during the ADQ, and the reporting frequency, is defined in the QAPP and/or Test Plan, based on the frequency of data reporting, the test duration, and the presence/absence of data quality issues

identified during the audits. Problems that could impact data quality are immediately communicated to the Program Coordinator and the MERC Director.

The results of the ADQ will be documented in a formal audit report:

- The draft ADQ report with the completed checklist will be submitted to the Program Coordinator and MERC Director within 10 days of the ADQ.
- The Program Coordinator audit response is due 10 working days from delivery of the ADQ report.
- The final ADQ, with audit responses, is due to MERC within 10 days of receiving the response.

The final report with Program Coordinator responses accepted by QA Manager will be signed and archived in the MERC database.

10.2.3.4. Data Validation

Data validation assesses the overall quality of a data set based on the MQOs. Data validation is initially conducted by the MERC Program Coordinator during the data review process. The Program Coordinator review includes verifying that:

- the raw data records are complete, understandable, well-labeled, and traceable;
- all data identified in the QAPP and Test Plan has been collected;
- instrument calibration and QC criteria were achieved;
- data calculations are accurate.

The Program Coordinator review may deem a data set unusable, questionable, or semi-quantitative, based on the results of the QC data and achievement of the DQIs. Data validation is also conducted during the ADQ when the MERC QA Manager reviews the data vs. QAPP/Test Plan requirements and assessed overall data quality. The ADQ verifies a percentage of the reported data vs. raw data, including any calculations. In addition, during the ADQ, the MERC QA Manager assesses, as appropriate:

- data completeness;
- sample handling, holding times, and integrity;
- instrument calibration;
- quality control;
- documentation.

Any limitations on the data and recommendations for limitations on data usability are documented in the data audit report.

10.2.3.5. Data Quality Assessment

The MERC Program Coordinator assesses data usability during the review of test data. This assessment includes a statistical and scientific evaluation of the data to determine the validity of the test design and the performance of the technology versus the performance measures specified in the QAPP and Test Plan design process. By using DQA, a reviewer can answer four important questions:

1. Can a decision (or estimate) be made with the desired level of certainty, given the quality of the data?
2. How well did the sampling design perform?
3. If the same sampling design strategy is used again for a similar study, would the data be expected to support the same intended use with the desired level of certainty?

4. Is it likely that sufficient samples were taken to enable the reviewer to see an effect if it was really present?

Assessments generally take place at one of two points in the data generation process. First, as data are generated, aspects of the project such as observation of field and laboratory operations, consistency of the data with MQOs, and/or successfully completing performance evaluation sample studies can be used to arrive as an assessment of whether the data are valid and acceptable. Once data have been examined and assessed, and they are found to be of known and acceptable quality, then the results can be evaluated in the context of the Data Quality Objectives for the test. An assessment must also be made as to whether there is a sufficient quantity of data to support test decisions, and whether the original sampling design was appropriate. In some cases, the data may suggest that additional data are required to achieve a higher statistical confidence level. This could be because too many data points were invalidated, that samples were not collected over a long enough time period, or that a vital sampling area not previously considered important, was missed. In other cases, an assessment might show that data of a different type are required, or that the sensitivity of the instrument used in the measurement was not adequate to meet test objectives. Thus, both types of assessments are vital to the successful completion of a BWTS test.

10.2.4. Assessment Reporting

Authority to effectively report TSAs, PEAs, and ADQs is assigned to MERC QA Manager. These written reports should:

- identify and document problems that affect quality and the achievement of objectives required by the QMP, QAPP, Test Plan, and any associated SOPs;,
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
- propose recommendations (if requested) for resolving problems that affect quality;
- independently confirm implementation and effectiveness of solutions;
- provide documented assurance (if requested) to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

Quality assessments of project activities are reported to the MERC Program Coordinator and Director. The Program Coordinator and the Director are responsible for ensuring that findings from these assessments of project activities are appropriately addressed.

10.2.5. Qualifications and Authority of Assessors

The principal MERC assessor is the MERC QA Manager, who will have an extensive quality assurance laboratory and field inspection background, and technical and management experience, and who will be directly familiar with MERC assessment requirements. The QA Manager must be independent of the work being reviewed, free of conflict of interest, and knowledgeable in the area being assessed. The QA Manager will have the responsibility and authority to:

- identify and document problems affecting the quality of BWTS test results;
- propose recommendations for resolving these problems;
- independently confirm implementation and effectiveness of solutions;
- recommend that work during a BWTS test be stopped if safety and quality are threatened.

10.3. Response

Responses to adverse findings should be addressed within 10 working days after an assessment report is completed. However, it is expected that findings that have a direct impact on the conduct of a verification test will be corrected immediately following notification of the finding. Responses to each adverse finding shall be documented in the assessment report. The response will indicate the corrective action taken or planned to address the adverse finding. The response should be signed and dated by the staff responsible for implementing the corrective action. The MERC Director reviews and approves the responses to the assessments and thus ensures that responses are thorough, fully address the audit findings and observations, and thoughtfully assess any impact to testing. Any corrective action that cannot be immediately implemented should be verified following completion by the MERC QA Manager. Once all corrective action associated with an assessment report has been taken, the MERC QA Manager will initial the corrective action in the assessment report thus documenting verification of the corrective action. Any impact that an adverse finding had on the quality of BWTS test data should be addressed in the test report.

10.4. Corrective Action

Corrective action is implemented in response to any situation that compromises the quality of testing or data generated by MERC. The need for corrective action can be identified by any MERC personnel and implemented with the prior approval of the MERC Program Coordinator and/or Director, in consultation with the QA Manager. Corrective action is required for all assessment findings and observations. The Program Coordinator is responsible for determining appropriate corrective action to address an issue. The corrective action should minimize the chance that a problem adverse to quality will re-occur. The corrective action will be documented by the Program Coordinator on the assessment report.

The Program Coordinator is responsible for ensuring that corrective actions are implemented as documented in the assessment report. The Program Coordinator provides a written response with objective evidence of the effectiveness of the correction, and with specified time frames for those actions in progress or planned for the future. Implementation of corrective actions must be verified by the MERC QA Manager to ensure that corrective actions are adequate and have been completed. Verification of corrective actions can be by re-assessment or examination of documentation. The assessment report cannot be finalized until each corrective action has been identified and verified.

The corrective action process should include an assessment of the root cause of a problem so that effective changes can be implemented to minimize reoccurrence. Once the root cause determination is verified, appropriate actions can be planned, documented, and implemented by the MERC staff.
Any finding that is a QAPP or Test Plan deviation must be documented.

10.5. Dispute

If an audit finding or response creates a dispute that cannot be resolved by the QA Manager and Program Coordinator, the dispute will be elevated to the MERC Director.

11. QUALITY IMPROVEMENT

MERC is committed to a process of continuous quality system improvement. While every member of the MERC team is encouraged to contribute to quality improvement initiatives, the MERC Director and the MERC QA Manager are specifically responsible for identifying opportunities to improve the quality system. The purpose of quality system improvement is to ensure that conditions adverse to quality are prevented, identified, corrected, documented, and tracked.

11.1. Annual QMP Review

An annual review of the MERC QMP will be conducted by the MERC QA Manager and research, technical, and management staff in order to incorporate improvements to the quality system process. Any revisions to the QMP will be compiled by the MERC QA Manager for review. Action items identified during the review will be documented by inclusion in the revised QMP. The QMP review will be documented by the MERC QA Manager and MERC Director by signing and dating the revised QMP routed for review and approval.

11.2. Problem Identification and Resolution

Detecting and correcting quality system problems is a result of qualified MERC technical and management staff implementing not only this QMP, but also the QAPP, Test Plans, and other procedures. All staff is encouraged to identify problems and offer solutions to problems in the following quality areas:

- adequacy of the quality system, as defined in the QMP;
- consistency of the quality system;
- implementation of the quality system to specific BWTS tests;
- correction of quality system procedures;
- completeness of documented information;
- quality of data;
- quality of planning documents, such as the QAPP or Test Plans;
- implementation of the work process.

Suggestions are received by the MERC Director and MERC QA Manager. No formal tracking system has been developed because suggestions are typically implemented in near-real time. The process for identifying and implementing improvements includes the following:

- Improvements to Test plans, test reports, and audit reports are made on the next new document of each type, which then becomes the template for future documents.
- Suggestions for improving sampling designs or test logistics are communicated during MERC team meetings.
- The Program Coordinator communicates improvements, lessons learned, and new instructions to the MERC team.
- Any team member may request a corrective action, if an on-going problem or systematic issue is identified.

11.3. Assessments

TSAs and ADQs serve as tools to determine cause and effect relations of significant problems that might require testing protocol, management system, or quality system changes. Monitoring and evaluation by the MERC QA Manager, for example, may indicate trends or common and recurring problems for an

entire technology evaluation. In this case, the situation is immediately communicated to the MERC Director and an appropriate corrective action identified.

11.4. User Feedback

Quality processes are continually monitored and both short-term and long-term quality issues are identified through feedback from vendors, regulatory agencies, academic institutions, classification societies, etc. Program review and internal lessons learned will be on going. Action items are reviewed by all levels of management each quarter.

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APPENDIX A

KEY MERC PERSONNEL

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QA Manager	Earle Buckley	843-991-2751, earlebuckley@comcast.net
SERC Co-PI	Greg Ruiz	443-482-2227, ruizg@si.edu
WREC Co-PI	Dan Fisher	410-827-8056, dfisher2@umd.edu
UMD Co-PI	Anwar Haq	301-405-7428, huq@umd.edu
ODU Co-PI	Fred Dobbs	757-683-5329, fdobbs@odu.edu

APPENDIX B

AGREEMENT TO PARTICIPATE IN A

MERC TREATMENT PERFORMANCE EVALUATION

This Agreement to Participate in an Evaluation is entered into this ___ day of _____, 2009 between the Maritime Environmental Resource Center ("MERC"), P.O. Box 38, Solomons, Maryland 20688, and _____ ("Participant"), _____ (address), (collectively, the "Parties").

RECITALS

WHEREAS, in [DATE], MERC issued a Request for Technologies that invited manufacturers of Ballast Water Treatment Systems to participate in an independent testing program designed to verify the performance of commercially available Ballast Water Treatment Systems (the "Program"), and

WHEREAS, after reviewing and considering the Request for Technologies, the Participant submitted an application seeking to participate in the Program, and

WHEREAS, MERC reviewed and accepted the Participant's application and conducted an evaluation of the Participant's Ballast Water Treatment System(s), and

WHEREAS, MERC and the Participant now wish to proceed with the Program on the terms set forth below,

NOW THEREFORE, in consideration of the mutual agreements and consideration set forth in this Agreement, the receipt and adequacy of which both hereby acknowledge, the Parties agree as follows:

1. Recitals. The Parties incorporate the foregoing recitals as part of this Agreement.

2. Evaluation Protocols. Evaluation Protocols include MERC Quality Assurance Project Plan (QAPP), Standard Operating Procedures (SOPs) and Product specific

Test Plan. The Parties understand, acknowledge and agree to participate in the Program as set forth in the Evaluation Protocols, a copy of which are attached as Schedule A to this Agreement and incorporated by reference herein. By executing this Agreement, the Participant understands, acknowledges and agrees that it:

(a) has had an adequate opportunity to review, analyze and consider one or more drafts of the Evaluation Protocols and to submit comments and objections before the Evaluation Protocols took its final form;

(b) is satisfied that the final Evaluation Protocols, as attached and incorporated into this Agreement, and the terms and conditions set forth in this Agreement are fair, objective and reasonable; and

(c) will abide by all terms and conditions set forth in the Evaluation Protocols and this Agreement.

The Participant further understands, acknowledges and agrees that it shall not withdraw or attempt to withdraw its participation in the Program at any time after executing this Agreement.

3. Amendments to Evaluation Protocols. The Participant understands and acknowledges that the development of the Evaluation Protocols has been a collaborative process involving itself, MERC, and other potential Participants, and that the final Evaluation Protocols embodies a protocol on which all have agreed, and to which all have agreed to abide. In order to maintain the integrity of the Program, the Participant understands, acknowledges and agrees, therefore, that the Evaluation Protocols cannot and will not be amended after the Program has begun under any circumstances, foreseen or unforeseen, without the express and unanimous written consent of MERC and all Participants.

4. The Product(s). The Parties agree that the Participant has submitted, and MERC has accepted, the following product(s) (the "Product(s)") for testing pursuant to the Treatment Performance Evaluation: [INSERT NAMES/IDENTIFYING SPECS OF PRODUCTS, QUANTITIES, AND WHATEVER OTHER INFORMATION WE WANT HERE]

5. Evaluation Reports and Participant Comments. The Parties understand, acknowledge and agree that the end product of the Program will be an Evaluation Report for the Product submitted for testing, and the Evaluation Report will be submitted to the Maryland Port Administration (MPA) and the Maritime Administration (MARAD) posted and will be publicly available on MERC's website. By executing this Agreement, the Parties understand, acknowledge and agree as follows:

(a) MERC will prepare the Evaluation Report for each Product, according to criteria set forth in the Evaluation Protocols;

(b) MERC will provide the Participant by e-mail or facsimile, as the Participant directs, a copy of the Evaluation Report thirty (30) days before MERC posts the Evaluation Report on the MERC website;

(c) MERC will post the Evaluation Report on its website without amendment, although MERC reserves the right to correct typographical and grammatical errors; and

(d) upon request from the Participant in writing, MERC may decide to include comments submitted by the Participant, up to two page in length, as an appendix to the Evaluation Report, but the decision to include or not to include any such Participant comments lies exclusively with MERC and at its sole discretion.

5. Ownership, Delivery, and Maintenance of the Product(s). The Parties understand, acknowledge and agree that the Product(s) shall at all times remain the property of the Participant. The Participant warrants that it has good title to the Product(s) and that the Product(s) do not infringe upon any patents, copyrights or other intellectual property rights of a third party. The Participant agrees to deliver the Product(s) to MERC, at its offices or as otherwise agreed, in new condition and good working order. Upon acknowledging receipt of the Product(s) from the Participant, MERC shall utilize the Product(s) as necessary to carry out the

Evaluation Protocols and shall maintain the Product(s) in good working order until the Program is completed.

In the event the Product(s) are not in good working order or if the Product(s) break or malfunction in the course of carrying out the Evaluation, MERC shall notify the Participant but not repair or replace the Product. The Participant understands, acknowledges and agrees that it, not MERC, shall be liable to any third parties damaged or injured by any breakage or malfunction of the Product(s) that occurs in the course of the Program, or for any infringement by the Product(s) upon any patents, copyrights or other intellectual property rights of any third party. The Participant further agrees to indemnify and hold MERC and its directors, officers, agents, employee, representatives, predecessors, successors, affiliates, and assigns harmless from any liability, including reasonable attorneys' fees, relating to or arising from any such breakage or malfunction of the Products in the course of the Program or any infringement by the Product(s) upon any patents, copyrights or other intellectual property rights of any third party.

6. Ownership of Data. The Parties understand, acknowledge and agree that Evaluation Statements will include data summaries and statistics on instrument performance, and further agree that all raw data collected from Product(s) in connection with the Program are the joint property of MERC and the Participant and shall be disclosed by MERC only to the Participant, unless the Participant otherwise requests in writing. The Participant hereby agrees that MERC may maintain in its files a copy of all data collected in the course of the Program in order to memorialize, verify and defend the results of the Program.

7. No Endorsement or Recommendation. The Participant acknowledges that through the Program, MERC does not make any recommendations, comparisons or endorsements of specific instruments. The Participant shall neither claim nor even imply to anyone that the Evaluation Reports prepared by MERC make any conclusions as to the relative performance of instruments. If the Participant decides to interpret the results or make conclusions as to the relative performance of another treatment system, the Participant must

make clear that these conclusions were not made by MERC and are solely the Participant's interpretation of the Program data.

8. Use of Logos. While MERC's logo may appear on the Evaluation Reports, the Participant is not permitted to use MERC's logo in any materials the Participant develops, without first obtaining MERC's authorization. In addition, the Participant acknowledges that MERC does not have the authority to grant the Participant any right to use the name or logo of MPA, MARAD or any other partner in the MERC effort.

9. Release. The Participant, for itself and its directors, officers, agents, employees, representatives, predecessors, successors, affiliates and assigns, hereby fully and irrevocably releases MERC and its directors, officers, agents, employees, representatives, predecessors, successors, affiliates and assigns from all claims, damages, causes of actions, liabilities relating to the Program, including but not limited to MERC's use of the Product(s), the results of the testing and MERC's publication of all Evaluation Reports (with or without Participant comments).

10. Entire Agreement. This Agreement constitutes the sole and complete agreement among the parties with respect to the Program, and it may not be modified except by a writing signed by both Parties.

11. Counterparts. This Agreement may be executed in two or more counterparts, including by facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

12. Authorization. Each of the signatories below represents and warrants that he or she is authorized to execute this Agreement on behalf of the entity for which he or she has signed.

MARITIME ENVIRONMENTAL
RESOURCE CENTER

DATE: _____ By: _____

Dr. Mario N. Tamburri

Title: MERC Director

[PARTICIPANT]

DATE: _____ By: _____

Title: _____

APPENDIX C

Maritime Environmental Resource Center
Research Services Application Form

NOTE: Only complete applications and attachments with full author reference information will be considered; other applications and attachments will be returned to the applicant. The total length of the application form is not to exceed 20 pages.

APPLICANT INFORMATION

Organization/Company:

Street:

City, State, Zip:

Phone:

Web Page:

Project Officer*:* Financial Officer:

Telephone: Telephone:

Fax: Fax:

E-mail: E-mail:

ORGANIZATIONAL DESCRIPTION

Tax Status: _____ Tax ID#: _____ Fiscal Year: / to /

(e.g., For-profit corporation, Individual, etc.) (month/day) (month/day)

Brief description of Business/Organizational History:

SUBMISSION INFORMATION

- Applications submitted for 2012 General Research Services by:
  5 PM EST 23 September, 2011 qualify for November 4, 2011 award notification

Today's date is: / /

(month/day/year)

A NOTE ON SUBMITTING THIS FORM AND ATTACHING DOCUMENTS

Submit your completed application electronically via email to Dr. Mario Tamburri, MERC Director, at tamburri@umces.edu. Attach all supporting information and reference documents in PDF format to the email prior to sending. Clearly label each document with the application question to which it corresponds and include full author reference information. Also, list the title of the attachment in the appropriate response text boxes within the application. Please note that incomplete application forms and attachments without full author reference information will be disregarded and returned to the applicant.

TREATMENT SYSTEM INFORMATION

I. PATENTS

Is the technology/methodology proprietary?	___Yes / ___No
Is the technology/methodology patented, copyrighted, licensed or otherwise protected?	___Yes / ___No
Is there any specific information regarding your technology/methodology or company that you wish to be treated as strictly confidential? If Yes, please describe (no confidential data please). ___Yes / ___No	

II. STATE OF DEVELOPMENT OF THE TREATMENT SYSTEM

Indicate the overall stage of treatment system development for the subject system (please check all boxes that apply), and also explain your response in the space provided.

☐ Product Definition ☐ Proof of concept ☐ Working Model ☐ Engineering Prototype

☐ Other (please explain)

If at the stage of “Engineering Prototype” what steps have been taken? Please check all boxes that apply and also explain your response in the space provided.

☐ Scale up ☐ Test ☐ Refine ☐ Production Engineering ☐ Product Safety Engineering

III. GENERAL DESCRIPTION OF TREATMENT SYSTEM

A. Provide a general description of the proposed BWT system including treatment stages, treatment processes, physical configuration, materials of construction, and integration with the shipboard ballast system.

B. Discuss the range of shipboard or shore-side applications for the proposed BWT system, including sizes and types of ships for which it would be intended, uptake versus discharge treatment, standard treatment capacities, new or retrofit shipboard applications, etc.

IV. SYSTEM PERFORMANCE AND OPERATION INFORMATION

A. Research has been conducted on this treatment system in the following categories (check all that apply). Supporting studies with full author reference information should be attached for each item checked.

	Fresh	**Brackish**	**Salt**
1. Bench-treatment effectiveness			
Zooplankton			
Phytoplankton			
Bacteria			
2. Bench-eco-toxicity			
Zooplankton			
Phytoplankton			
Bacteria			
3. Shore-based performance			
Zooplankton			
Phytoplankton			
Bacteria			
4. Ship-board performance			
Zooplankton			
Phytoplankton			
Bacteria			

5. Operational effects on			
Corrosion			
Ballast throughput			
Energy consumption			
Crew time			

Names of attached supporting studies (with category number reference included in file name):

B. Environmental Soundness (i.e., the proposed ballast treatment system will not require regulatory discharge permits for operation in U.S. or Canadian waters; or, routine and prevalent use of the proposed treatment system as a ballast treatment method would not otherwise result in acute or cumulative degradation of environmental quality of receiving ecological systems.)

Please describe what is known about the environmental soundness of the proposed system.

	Yes	**No**	**Maybe**
Routine use will require a regulatory permit.			
Environmental soundness will be influenced by voyage duration, ship condition, or salinity of ballast water or receiving waters			
Treatment residue and/or by products will completely degrade prior to discharge into the receiving system.			
Treatment residue and/or by products will require dilution to render them harmless to a receiving system.			
Treatment residue and/or by products will be equally environmentally sound in the context of fresh and salt water.			

Please use the space below to provide any explanation for your responses.

C. Biological Effectiveness (i.e., the treatment system will yield dependable reductions in live biological material surpassing the IMO standard, and any other prevailing standards that may be stricter; or will significantly reduce ballast transfers of harmful microbes and viruses.

Please indicate the probable scope of effectiveness of the treatment system.

	Yes	No	Maybe
The treatment system will significantly reduce live zooplankton from ballast water discharge.			
The treatment system will significantly reduce live phytoplankton in ballast water discharge.			
The treatment system will significantly reduce microbes and viruses in ballast discharge.			
The treatment system effectiveness will likely be affected by salinity			
The treatment system effectiveness will likely be affected by voyage duration.			
The treatment system effectiveness will likely be affected by ship condition (BOB vs. NOBOB).			

Please use the space below for any additional narrative information.

D. Automated System Monitoring Mechanism

Please indicate the state of planning associated with automated monitoring of treatment system function in operational settings. Please attach (and clearly Identify as "Supporting Information for Question III D") all findings/supporting information related to anticipated moniterability of the proposed treatment system.

☐ No planning yet undertaken ☐ Monitoring concept in place ☐ Monitoring system developed

Please describe the monitoring concept in the space provided below.

E. Operational Practicability (i.e., the proposed treatment system is compatible with the physical ship environment in terms of its physical footprint and power or other physical requirements, will operate effectively and efficiently in the environment of a commercial vessel for an extended period of time (i.e., 10 years); and will not impose in crew safety concerns.)

Please indicate by checking the appropriate box the degree to which the treatment system has been adapted to maritime applications. Please attach (and clearly Identify as "Supporting Information for Question III E") all findings/supporting information related to operational practicability of the proposed treatment system.

☐ No evaluation yet undertaken ☐ Some initial planning in place ☐ System fully marinized

In addition, please provide your best estimates regarding the following questions:

1. What could the onboard physical configuration of the BWT system be, including general arrangement of installed equipment?

2. Could the system be installed in an existing ship? If so, will system installation in an existing ship likely require vessel dry-docking?

3. What, if any, special utility connections (power, water, air), interconnections with shipboard piping and equipment, storage requirements, other ancillary requirements, may be required for operation of this system in a ship?

4. What electrical, instrumentation and control (EI&C) components may be required to operate the proposed BWT system in a ship?

5. What are your plans regarding how can these components may be integrated with the existing shipboard ballast system, including:

   - Power demand?

   - Main and local control panels?

   - Power distribution system?

   - Power quality equipment?

   - Instrumentation and control system architecture?

   - Process control?

6. What health and safety risks may be associated with proposed BWT system, including materials storage, handling and disposal? What health and safety certification/training may be required for system operators? Please attach the MSDS for any chemical components of the treatment system.

7. What start-up, normal and emergency operating and shutdown procedures may be required for the BWT system?

8. What do you believe the overall reliability of the proposed BWT system (e.g., percent downtime per 1,000 hrs of operation) will be?

F. Cost-Effectiveness (i.e., the proposed treatment system will not bear significant net costs relative to other types of ballast treatment, considering effects on ballasting time, crew time demands, capital costs, operating costs, or structural decay)

Please indicate the state of knowledge associated with the extent to which operation will:

1. Significantly slow ballasting rate (please check one);

☐ Unknown ☐ Unknown but reason to believe not significantly ☐ Certain not significantly

2. Add significantly to crew time demands (please check one);

☐ Unknown ☐ Unknown but reason to believe not significantly ☐ Certain not significantly

3. Require significantly higher capital cost for purchase, operation (including consideration of any structural impacts on ships) and/or installation than other ballast systems (please check one);

☐ Unknown ☐ Unknown but reason to believe not significantly ☐ Certain not significantly

Please attach (and clearly Identify as “Supporting Information for Question F1, 2, or 3, as appropriate”) all findings/supporting information.

G. Research and Development Needs

Describe the research and development needs that you would like addressed through MERC research services.

V. PROJECT INSTALLATION SCHEDULE

1. Please indicate **the number of days** lead time you would require following any notice of award to deliver a treatment system capable of 300 m^3/hour flow rates.

2. Please indicate **the number of days** required to commission the equipment for testing at the site once delivered.

3. Will you be able to provide a system representative qualified to respond to any mechanical issues that may arise around system operation to be present at the site during hook-up and testing?

   Yes No

VI. ATTACHMENT

Ensure the following attachments are included with your application.

☐ One of the following for any private entity:

a. Professional references (3 or more), and, if relevant,
b. Most recent audited financial statements;

☐ Notification of any SEC, IRS or other government agency review, investigation or actions.

☐ Proof of appropriate insurance against liability for injury to persons or property.

☐ Certificate of Incorporation (if applicable).

☐ Correctly labeled supporting information/relevant attachments with full author reference information.

VII. SIGNATURE OF APPLICANT

I certify that the above information is true and accurate.

_____ _____

Signature of Executive or Project Officer *Date*

_____

Name, Title

APPENDIX E

DATA QUALITY INDICATOR DEFINITIONS and EXAMPLES

Data Quality Indicator	Meaning	QC Measures
Precision	Agreement among repeated measurements under identical, or substantially similar conditions	• Field duplicates or splits • Lab duplicates/replicates • Can be within same organization or among organizations using the same or different methods
Bias	Systematic or persistent distortion of a measurement process that causes errors in one direction	• Instrument calibration standards • Lab QC spikes • Matrix spikes & duplicates)
Accuracy	Overall agreement of a measurement to a known value - includes a combination of random error (precision) and systematic error (bias) in both sampling and analysis operations	• Matrix-specific standard or certified reference materials • Spiked matrix samples
Representativeness	The degree to which data accurately and precisely represent a characteristic of a population or condition	• No specific QC tools to measure • Evaluate if samples were collected and measurements made in such a way that they reflect the population of interest (as specified in the QAPP)
Comparability	Measure of confidence that one data set can be compared to another and combined for the decision(s) to be made	• Split samples; existing data • Compare population targeted by sampling techniques; sample collection, handling, preparation, & analysis procedures; holding times, stability issues, QA protocols
Completeness	The amount of valid data needed to be obtained from a measurement system	• # of valid results vs. the number determined to be necessary during project planning (as specified in the QAPP)
Specificity	Correct identification of the parameter you are targeting	• Retention times • Ion abundance ratios • Confirmation analyses • Peak shape
Detection and Quantitation	The ability to • Determine if it is there or not • Distinguish between responses representing different concentrations of interest	• Method Detection Limit (MDL) or equivalent • Signal to noise ratios • Calibration range • Analysis of samples at/near quantitation limit • Well below action level

APPENDIX F

QAPP QA/R-5 ELEMENTS AND PREPARATION GUIDANCE

EPA QA/R-5 QAPP Element	Description for Section
GROUP A: PROJECT MANAGEMENT	The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.
A1 Vendor Approval Page	Includes the vendor name, company, and date.
A2 Table of Contents	Table of Contents
A3 Distribution List	Distribution list typically includes vendor, EPA peer reviewers, collaborators and other stakeholders, and Battelle testing staff.
A4 Verification Test Organization	This section should identify and define responsibilities for the EPA and Battelle managers and QA managers, the VTC, stakeholders, and testing staff. Their involvement in the test should be described. Include an organization chart that shows lines of authority, responsibility, and communication. Subcontractor task leaders should be included.
A5 Background	This section should describe the technology need and technology description.
A6 Verification Test Description and Schedule	• Define the test schedule • Test sites/locations • Health and safety considerations
A7 Quality Objectives and Criteria for Measurement Data	This section should define the test Data Quality Objectives (DQOs), the data quality indicators (DQIs) that will be used to assess data quality, and the Measurement Quality Criteria (MQOs) that define the criteria by which data acceptability will be used assessed
A8 Special Training/Certification	Special Training/Certification
A9 Documents and Records	This section should describe the controlling documents for the project and other documents that will be generated during the project. The section should also define the records that will be kept during the project, how they will be maintained, and their final disposition.
GROUP B: DATA GENERATION AND ACQUISITION	The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented
B1 Experimental Design	Outline the experimental design, including test procedures, sampling design and rationale, sampling frequencies, matrices, and measurement parameters of interest; define supporting documents (e.g., SOPs). Any statistical analysis planned for the data should be described.
B2 Sampling Methods Sampling Methods (collection and approach) details, including applicable SOP citations.	Sampling Methods (collection and approach) details, including applicable SOP citations.
B3 Sample Handling and Custody	This section should describe the sample handling and custody procedures that will be implemented for the collection of environmental samples. • Sample Handling and Custody (Describe procedures for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples). • Sample Identification numbers and labels

EPA QA/R-5 QAPP Element	Description for Section
B4 Reference Method	This section should define the reference method against which technology results will be assessed. It should define how, when, and from where data will be obtained. It should identify any constraints on the data collection process. It should address, where appropriate: • Analytical Methods (identify analytical methods and equipment for the study, including method performance requirements and applicable SOPs) MDLS, method details, including applicable SOP citations.
B5 Quality Control	This section should specify the activities during data collection that will provide the information used to assess data quality (i.e., field or laboratory QC operations, audits, technical assessments). Specifically, it should address: • QC (Describe QC procedures that should be associated with each sampling and measurement technique. List required checks and corrective action procedures).
B6 Instrument/Equipment Testing, Inspection, and Maintenance	This section will describe the maintenance procedures required for equipment or instruments used to collect or measure environmental data. Details should include: Instrument/Equipment Testing, Inspection, Maintenance, Frequency, and Acceptance Criteria. It is usually acceptable to reference a specific SOP, rather than provide details in the QAPP. However, if specific maintenance is critical to an operation the project leader may choose to highlight those procedures in the text.
B7 Instrument/Equipment Calibration and Frequency	This section should describe the calibration of equipment or instruments used to collect and/or measure environmental data. Details should include: Instrument/Equipment Calibration, Frequency, and Acceptance Criteria. It is acceptable to reference SOPs for routine calibration procedures. However, the criteria for critical measurements should be defined in the QAPP.
B8 Inspection/Acceptance of Supplies and Consumables	Inspection/Acceptance of Supplies and Consumables (Define how and by whom the sampling supplies and consumables will be accepted for use in the project).
B9 Nondirect Measurements	Nondirect Measurements (existing data) (define the criteria for the use of nonmeasurement data, such as data that come from databases or literature).
B10 Data Management	This section should describe how data collected during and after testing will be documented, managed, stored, and controlled. Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data. Describe data reporting conventions, including the use of data qualifiers and units).
GROUP C: ASSESSMENT AND OVERSIGHT	The elements in this group address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.
C1 Assessment and Oversight	This section should describe the assessment activities that will be implemented for the project. This will typically include PEs, TSAs, and ADQs.
C2 Reports to Management	This section will identify the frequency, content, and distribution of reports issued to keep management informed of the results of audits and assessments.
GROUP D: DATA VALIDATION AND USABILITY	The elements in this group address the activities that occur after the data collection or generation phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.
D1 Data Review, Verification, and Validation	Describe the types of data review, verification, and validation that will be implemented for the study.
D2 Validation and Verification Methods	Define the data validation and verification procedures and the criteria used to accept or reject the data based on quality.